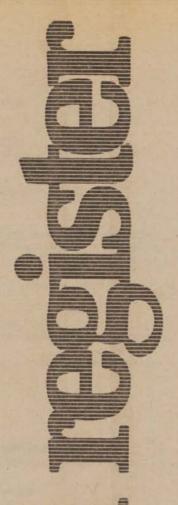
7-30-86 Vol. 51 No. 146 Pages 27147-27396



Wednesday July 30, 1986





FEDERAL REGISTER Published daily, Monday through Friday, (not published on Saturdays, Sundays, or on official holidays), by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

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How To Cite This Publication: Use the volume number and the page number. Example: 51 FR 12345.

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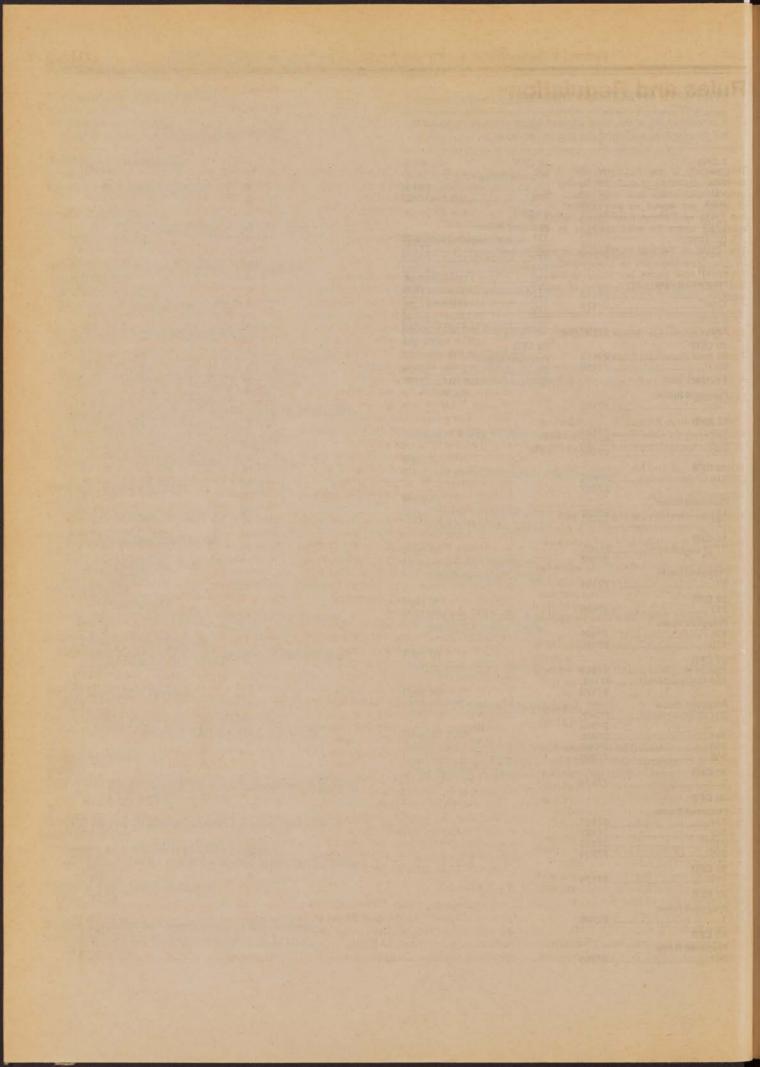
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week.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 235

[Amdt. No. 14]

Child Nutrition Programs; Revision of Requirements Governing Availability of State Administrative Expense Funds

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: In this rule the Food and Nutrition Service (FNS) changes the manner in which State Administrative Expense (SAE) funds are made available for payment to State agencies by integrating a broadened State agency SAE plan into the SAE funding process. This rule provides the regulatory basis for an overall SAE Management System which will enable FNS to more effectively manage SAE funds. Under this rule, the amount of SAE funds made available for payment to a State agency in any fiscal year will be based on the amount justified in the annual State agency plan (including any amendments thereto) as approved by FNS, but shall not exceed the total of amounts allocated, reallocated or transferred to the State agency during the year plus prior year carryover. FNS will monitor State agency implementation of annual plans as an integral part of its ongoing management evaluation process and State agencies may be subject to the SAE sanction provisions for failure to implement approved plans to the extent practicable. This rule also includes provisions regarding the reallocation of SAE funds, State funding requirements, and the transfer of SAE funds to distributing agencies.

EFFECTIVE DATE: August 29, 1986.

FOR FURTHER INFORMATION CONTACT: Lou Pastura, Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Alexandria, Virginia 22302; telephone (703) 756–3620.

SUPPLEMENTARY INFORMATION:

Classification

This final rule has been reviewed under Executive Order 12291 and has been classified as not major because it does not meet any of the three criteria identified under the Executive Order. This action will not have an annual effect on the economy of \$100 million or more, nor will it result in major increases in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions. Furthermore, it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.based enterprises to compete with foreign-based enterprises in domestic or export markets.

This rule has also been reviewed with regard to the requirement of the Regulatory Flexibility Act (5 U.S.C. 601–612). The Administrator of the Food and Nutrition Service has certified that this rule will not have a significant adverse economic impact on a substantial number of small entities.

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3520), the recordkeeping and reporting requirements contained in § 235.5 (b), (c) and (d) and in § 235.7(b) of this final rule have been submitted to the Office of Management and Budget (OMB) for approval. Current recordkeeping and reporting requirements for Part 235 were approved by OMB for use through September 30, 1986. (OMB Nos. 0584–0067 and 0584–0319.)

This activity (SAE) is listed in the Catalog of Federal Domestic Assistance under No. 10.560 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. (See 7 CFR Part 3015, Subpart V, 48 FR 29112, June 24, 1983.)

Background

On March 25, 1986, FNS published a proposed rule in the Federal Register (51 FR 10214) that was primarily concerned with revising existing SAE plan provisions. These changes were considered essential to the successful implementation of an overall SAE management system that was under development by FNS. Under this system, the annual SAE plan would be integrated into the SAE funding process. It would, upon approval by FNS, serve as the basis for determining the amount of SAE funds actually made available for payment to a State agency. The plan would contain information, not previously provided, but considered necessary for meaningful plan review and approval by FNS. The revised plan would also assist FNS in assessing State agency use of SAE funds as part of its Federal oversight responsibility.

Under the proposed rule a State agency could amend its annual plan at any time during the fiscal year to justify additional SAE funds up to the amount allocated to it for the year plus carryover from the previous year. Amendments could also be made to incorporate reallocated SAE funds or to address any other changes in funding or funding needs. Amendments would be subject to the same review and approval process as the plan itself. The proposed rule would also require a State agency to implement its annual plan to the extent practicable and cited failure to substantially implement the plan as cause to subject the State agency to the existing SAE sanction provisions.

The proposal also contained several other provisions not directly related to the annual plan. They were: a reduction in the number of authorized SAE reallocations from two to one per year; incorporation of Office of Management and Budget (OMB) and the United States Department of Agriculture (USDA) costsharing and matching requirements within the SAE State funding (maintenance of effort) provisions; a provision that in-kind contributions may not be counted toward the SAE State funding requirement; a provision requiring the reporting of State funds usage; and a provision removing certain restrictions on the transfer of SAE funds to distributing agencies.

In response to the proposed rule, FNS received 26 non-USWDA comments—25 from State agencies and 1 on behalf of the State Child Nutrition Directors in one FNS Region. These comments represent imput from 27 of the 83 State agencies that are currently eligible to receive SAE funds and thus subject to the provisions of Part 235. FNS would

like to thank all commenters who responded to the proposal. Generally, commenters were opposed to the proposed rule with the degree of opposition ranging from dissatisfaction with the entire proposal to concern over one or more specific provisions. All comments received were carefully considered in formulating this final rule. Every effort was made to incorporate into the rule commenter recommendations which improved or clarified the overall approach to improving the management of SAE funds that was set forth in the proposed rule. Although several commenters felt that no change should be made in the manner in which SAE funds are currently managed, FNS is committed to the belief that an integrated SAE Management System, by providing better accountability and control, will promote more effective and efficient use of these resources.

The remainder of this preamble will address general and specific commenter concerns relative to the various provisions of the proposed rule and will discuss modifications or clarifications that are being made under this final rule. For ease of reference, commenter concerns and changes made, as applicable, are presented under headings which represent the significant provisions of the proposed rule.

1. Method of Payment.

The proposed rule would revise the method of payment provision of the SAE regulations to reflect the grant award process currently in use for all Child Nutrition Programs. The proposal specified that the availability of SAE funds through Letters of Credit would be dependent on the approval of annual plans and provided for advances in the event that plan approval was delayed. Eight commenters addressed this provision. Six expressed concern that approval delays and uncertainties over the availability of SAE funds would adversely affect program administration. Commenters cited additional paperwork and decreases in FNS staff as potential causes for delay and pointed out that no turn-around time for approval was given, that State agencies would have no assurances that their plans/ amendments would be approved, and that no guidelines for advances were provided. Three commenters felt that limiting State agency access to SAE funds was contrary to section 7 of the Child Nutrition Act (CNA).

In response, FNS would like to alleviate commenter concerns in this area. As discussed later in this preamble, this final rule has been modified to minimize additional

paperwork burdens. Furthermore, FNS Regional Offices will be coordinating closely with State agencies while plans are being prepared and cleared within the States in order to facilitate the clearance and approval of the plans when they are submitted to FNS. The timely clearance and approval of these plans will be given high priority. However, if approval is delayed, advances of SAE funds can be made under this rule. The amount of such advances will be determined based on consideration of a State agency's past as well as anticipated SAE funds usage. Finally, FNS believes that the method of making SAE funds available for payment to States under this rule is in conformity with section 7 of the CNA. Section 7 requires the Secretary to make SAE funds available to the States but also requires that States submit to the Secretary for approval annual plans for the use of SAE funds. This is the basis for the current rule which requires plan approval prior to the release of SAE funds. While the proposed rule would go one step further, limiting the amount of SAE funds put into a State's Letter of Credit, this does not serve to limit State agency access to the funds. Upon proper justification through plans and amendments, the entire SAE allocation is available. FNS believes that this linking of SAE funds availability to funding requirements reflected in SAE plans under this rule is consistent with these legislative provisions. Therefore, § 235.5(a) has been retained essentially as proposed. Minor changes have been made, however, to make it clear that the State agency's grant of SAE funds is based on amount allocated, reallocated and transferred to it; and to include references to plan amendments in provisions dealing with plan approval and availability for payment of SAE

2. Expanded Administration Plan

The proposed rule contained provisions that would require the reporting of additional information by State agencies. Specifically, it was proposed that State funds be included in the plan and that projected expenditures by program and activity be provided. Comments from 23 of the 26 commenters were received on these provisions with 3 commenters expressing their support and 20 expressing opposition or concern. Several commenters questioned either the authority or appropriateness of FNS to require the additional information. Some of these expressed the view that such additional information was excessive and unnecessary and would create a paperwork burden that was contrary to the intent of the Paperwork

Reduction Act of 1980 and/or Pub. L. 97–35 which eliminated the annual State Plan of Child Nutrition Operations. Several commenters indicated that for a variety of reasons it would be difficult for them to provide the additional information to the level of detail that they believed was required by the proposed rule. Some commenters stated that projecting expenditures by program and/or activity was not necessary for effective planning and management. Finally, a few commenters suggested an addition to or clarification of information required in the plan.

FNS recognizes the concerns of commenters in this area and, as such, will require only such additional information as it considers necessary to carry out an effective SAE Management System that is consistent with its overall Federal administrative responsibility. This final rule amends § 235.5(b) to require State agencies to include State provided funds in their plans since FNS believes that a meaningful assessment of planned SAE funds usage cannot be conducted without considering all funds that are available to the State agency. Similarly, information on State agency activity and overall program levels is needed not only to assess planned SAE usage but also to serve as a reference source when evaluating State agency performance during FNS conducted management evaluations. FNS acknowledges that the proposed rule was not clear as to the degree of detail to which activity and program information was to be reported. As a consequence, some commenters interpreted the proposal as requiring budget breakdowns by cost category within activity for each program. This final rule makes it clear that cost category information is not required for each activity or program but only in the form of totals (combined Federal and State funds) for each category. Similarly, only a total estimated amount is required for each activity as defined by the State agency. Finally, only a total estimated amount is required for each of three program areas (School Nutrition Programs, Child Care Food Program and Food Distribution Program). Only one figure showing the amount of State funds separately is required, i.e., the amount of total budgeted funds that are State funds. In keeping with commenter concerns, the rule also states that FNS guidance for preparing the plan shall provide flexibility in reporting with a minimal amount of reporting burden. However, in response to specific administrative deficiencies identified by FNS, the requirements in the guidance may be supplemented for individual

State agencies in order to obtain such additional information as may be necessary to address the deficiencies. Finally, this rule has been revised to remove the obsolete reference to "... system level supervisory and operating personnel, and school level personnel..." which was contained in the provision describing the required State staffing plan, and to add to the plan the total estimated amount of Child Care Food Program two percent audit funds to be used.

3. Availability of SAE Funds

Under the proposed rule, the amount of SAE funds that would be made available for payment to a State agency would be determined by FNS upon approval of the State agency's plan and would be limited to the amount justified in the plan or the State agency's SAE funds allocation plus carryover, whichever was less. Fifteen commenters expressed a variety of concerns over this provision and its effect on the carryover of SAE funds by State agencies. Some felt that the provision was contrary to the intent of section 7(e) of the CNA which authorized carryover and/or were concerned that the provision would limit State agency flexibility in the use of carryover funds. They pointed out the specific benefits of carryover in long-range planning, hiring, handling unforeseen expenditures, and in alleviating Federal funding uncertainties at the beginning of the fiscal year. Others felt that problems associated with excess carryover were not addressed by the proposal. Several commenters felt that it was not appropriate for FNS to judge program needs within each State in approving plans and wondered if FNS would restrict access to SAE funds if it did not approve of certain activities or if it would recover any funds that were not budgeted and approved at the beginning of the year.

The proposed rule was not intended to affect materially a State agency's right to carry over and use SAE funds. What was intended, however, was to establish better accountability for such funds through the plan process. Under the proposed rule, Federal control over carryover funds, as well as all other SAE funds, would be maintained until the funds were needed for obligation and expenditure by State agencies as evidenced in their approved plans. In effect, the funds would be held in reserve until needed. Funds not included in approved plans would not be recovered by FNS unless they were first released by State agencies. Under these conditions, State agencies would, with effective planning and budgeting,

continue to realize the benefits of carryover funds. In view of the broad legislative provision which authorizes carryover, FNS continues to believe that the above described proposal to improve the accountability and control of SAE funds is an appropriate part of its SAE Management System. This final rule essentially reflects the proposed provisions.

FNS acknowledges that State agencies have primary responsibility under their Federal-State agreements to determine program needs within their jurisdictions and, using available resources, to administer the programs in accordance with applicable legislation and, regulations, instructions and procedures set forth by FNS. However, as the Federal agency legally responsible for overall program administration, it is appropriate that FNS monitor all aspects of program administration by State agencies and work to improve such administration where necessary. This would be true whether or not SAE funds were being provided to State agencies. However, the provision of SAE funds further underscores the Federal concern with and commitment to effective and efficient State agency program administration. This final rule makes the SAE plan a critical component of FNS' oversight effort in this area. Approval of plans must be consistent with that effort. Therefore, under this rule FNS approval of plans or amendments shall be on the basis of consistency with program administrative needs and SAE requirements.

4. Plan Amendments, Reallocation and Transfer of SAE Funds

The proposed rule contained provisions that would enable State agencies to amend their plans at any time during the year in order to gain access to additional SAE funds within their grants. Other changes in funding or funding needs would also require plan amendments. Amendments, like the plan itself, would be subject to FNS review and approval. It was also proposed that the authorized number of required SAE Funds Reallocation Reports (FNS-525) be decreased from two to one and that requests for reallocated funds be treated as plan amendments. The rule also proposed that the reallocation reports be submitted between March 1 and May 1, the specific date to be set by FNS. Twelve State agencies commented on these provisions. Four commenters supported the concept of one reallocation with one of these also supporting the plan amendment provisions. Several commenters noted problems with timing for both reallocations and plan amendments.

Some felt that if a reallocation occurred after May 1, it would be too late for prior year (carryover) and/or current year funds. One commenter felt that such a reallocation would occur too early. With respect to plan amendments, several commenters cited lengthy State clearance procedures or overlapping Federal and State fiscal years as impediments to the submission of timely plan amendments. One commenter suggested that amendments be required to be structured so as to be consistent with the plan. Several commenters questioned the need for FNS approval of plan amendments not involving increased SAE funding. Finally, some commenters suggested that State concerns be obtained and considered by FNS when establishing reallocation guidelines and priorities.

FNS acknowledges that no one reallocation time would be entirely satisfactory for all State agencies. However, since a reallocation based on input from all State agencies is a complex and time-consuming operation, FNS believes that the number of such comprehensive reallocations should be limited to one in order to relieve administrative burdens and should be based on information received prior to the third quarter of the fiscal year in order to address both prior and current year funds. To meet any special needs that may occur at other times during the year, this final rule has been reworded to allow FNS to reallocate SAE funds at other times based on information other than the annual reallocation reports submitted by State agencies. Although FNS reserves the right to establish reallocation guidelines and priorities, it will seek and consider State agency input on this subject. In response to comments on the submission and approval of plan amendments, FNS has revised the final rule to require that amendments be in a format consistent with that of the plan and that only amendments justifying additional SAE funds or resulting in significant reductions in planned funding levels or levels of planned activity require FNS approval. This latter change should not only expedite the amendment process in many cases but will appropriately narrow FNS' scope of interest to matters that may adversely affect program administrative needs.

Finally, three clarification changes have been made in the final rule. First, the rule now requires that reallocated funds be covered by a plan amendment before they can be made available for payment through the Letter of Credit. Second, the rule allows State agencies to release SAE funds to FNS for

reallocation at any time during the year and not just when the annual reallocation report is submitted. Third, § 235.6(a) was revised to clarify the conditions under which a State agency may transfer SAE funds to another State agency (such as a distributing agency) within the State.

5. Plan Implementation and Monitoring

Under the proposed rule, State agencies would be required to implement their approved plans to the extent practicable; FNS would monitor implementation of plans through management evaluations, State agency reports or other available means; and State agencies would be subject to the sanction provisions of § 235.11(b) if they failed to substantially implement their approved plans. Twelve commenters responded to these provisions. One commenter supported the concept of monitoring the management of SAE funds through management evaluations while the others expressed concern over or opposition to these provisions. Commenters felt that FNS should monitor compliance with program regulatory requirements rather than the implementation of plans and were concerned that FNS would use the plan to direct and control State agency operations. They also felt that the proposed monitoring of plans would duplicate what is currently being done in management evaluations and through internal State review procedures. Some had specific concerns about how the monitoring would be done and cited reductions in FNS staff and resources, lack of guidelines on what constitutes acceptable plan implementation, and proposed additional reporting burdens as potential problems. With respect to sanctions, commenters felt that the failure to implement plans was not sufficient reason to invoke the SAE sanction provisions since such a failure would not necessarily indicate noncompliance with program regulatory requirements and might be beyond the control of the State agency.

FNS would like to point out that monitoring of plan implementation would not be done in lieu of program compliance monitoring but, rather, in conjunction with it and as part of the overall management evaluation process. In this regard, FNS has a responsibility to monitor State agency management of SAE funds. Since planning is an integral part of effective management, FNS believes that it should monitor and assess plan implementation. Such activity should not be viewed by State agencies as an attempt to direct and/or control State agency operations. In support of this and as previously

discussed in this preamble, changes have been made in this final rule to promote State agency flexibility in plan preparation and to limit FNS approval of amendments. Furthermore, State agencies may submit amendments to their plans at any time and FNS guidance on this subject will allow a degree of latitude in plan implementation without submission of amendments. With respect to specific commenter concerns on monitoring, FNS will place priority emphasis on implementing and maintaining the SAE Management System. Additional State agency reporting burden has been limited to the additional plan requirements, plan amendments as necessary, and the annual reporting of State funds usage.

FNS agrees with commenters that State agency failure to implement a plan cannot necessarily be equated to noncompliance with program regulatory requirements. However, such failure could indicate deficiencies in the management of SAE funds and, depending upon the degree of failure, may well affect the State agency's ability to meet program administrative needs and comply with regulatory requirements. FNS also agrees with commenters that, by itself, failure to implement a plan is not sufficient reason to subject a State agency to the SAE sanction provisions and has removed the proposed language in question. Readers should note, however, that this final rule still requires State agencies to implement their approved plans (as amended), to the extent practicable. Since this is a regulatory requirement, failure to comply may subject a State agency to SAE sanction under § 235.11(b). However, FNS believes that the language "to the extent practicable" provides an appropriate perspective from which to view and assess plan implementation.

6. State Funding Requirements

The proposed rule would incorporate the cost sharing and matching requirements of OMB Circular A-102 and USDA regulations (7 CFR Part 3015) into the SAE regulations, specify that inkind contributions could not be counted toward the SAE State funding requirement, and require State agencies to report State funds usage on the Financial Status Report (SF-269) in accordance with guidance provided by FNS.

Ten State agency commenters addressed these provisions. Two supported the reporting of State funds usage, one agreed that in-kind contributions should be excluded from State funding requirements, and the remainder expressed opposition or concern over one or more of the provisions or were unclear as to how the in-kind contribution or reporting provisions would be applied.

Two of these felt that in-kind contributions should not be excluded without specific legislative authority and two felt that information on State funds usage should be collected during

management evaluations.

Section 7(h) of the Child Nutrition Act requires States ". . . to maintain a level of funding out of State revenues, for administrative costs . . . not less than the amount expended or obligated in Fiscal Year 1977." This language clearly excludes in-kind contributions and funds from sources other than State revenues from being considered in meeting the State funding requirement. The Department acknowledges that in excluding only in-kind contributions from being considered, the proposal presented an incomplete picture and made it unclear as to what actually could be counted toward meeting this requirement. Therefore, the following changes are reflected in this final rule to make the State funding provisions consistent with legislation and to more clearly describe the applicability of OMB and USDA requirements. The reference to "Expenditures of funds from State sources . . ." in the provision setting forth the State funding requirement has been changed to "Expenditures of funds from State revenues . . ." and the language incorporating the OMB and USDA provisions has been changed to make it clear that not all of these provisions apply to the State funding requirement. With respect to reporting, the Department disagrees with commenters who suggest that management evaluations can be used to provide adequate information on State funds usage to FNS. Management evaluations of State agencies are conducted at various times throughout the year. Current year information collected during a management evaluation would likely be incomplete, and information collected for the prior year could be up to a year old depending upon when the management evaluation was conducted. Such a collection method would be inadequate for monitoring the State funding requirement or for year-end assessment of State plan implementation under the SAE Management System. Therefore, the requirement for reporting State funds usage on the Financial Status Report (SF-269) has been retained. Under the proposed rule, this information would have been reported at the end of each

fiscal year. However, the SF-269 is a quarterly report that is designed to provide information on a cumulative basis. The annual reporting of State funds usage would be inconsistent with other information being reported on this form and could prove to be confusing for both State agencies in providing the information and FNS when using it. Furthermore, due to overlapping State and Federal fiscal years, many State agencies would have to maintain this information on a quarterly basis in order to obtain an appropriate four quarter annual total. In view of this, FNS believes that quarterly reporting would result in minimal additional recordkeeping and reporting burdens nationally. Therefore, in order to integrate the reporting of State funds usage into the existing reporting system, this final rule provides for the quarterly reporting of such funds. FNS will provide guidance to State agencies on how this shall be accomplished.

7. Effective Date

In developing the SAE Management System, FNS has maintained its intention to fully implement the system in Fiscal Year 1987. Several commenters expressed concern about being able to comply with the submission date for a revised annual plan for Fiscal Year 1987 due to insufficient lead time for internal State clearance. In response to these commenters and to allow a 30-day period between rule publication and effective date, the final rule changes the due date for the Fiscal Year 1987 plans to September 2, 1986. The rule also allows FNS to grant individual extensions beyond plan due dates, if necessary. FNS will make every effort to expedite plan review and approval in order that Fiscal Year 1987 SAE funds can be made available for payment to State agencies through their Letters of Credit by October 1, 1986.

List of Subjects in 7 CFR Part 235

Food assistance programs, National School Lunch Program, School Breakfast Program, Special Milk Program, Child Care Food Program, Food Distribution Program, Grants administration, Intergovernmental relations, Reporting and recordkeeping requirements administrative practice and procedure.

Accordingly, Part 235, is amended as follows:

PART 235—STATE ADMINISTRATIVE EXPENSE FUNDS

1. The authority citation for Part 235 continues to read as follows:

Authority: Secs. 7 and 10, Pub. L. 89–642, 80 Stat. 888, 889 (42 U.S.C. 1776, 1779), unless otherwise noted.

- 2. In Part 235, all references to "SPD" are changed to read "CND".
- 3. In § 235.2, paragraph (p-1) is removed, paragraph (b) is revised and paragraph (n), previously reserved, is added as follows:

§ 235.2 Definitions.

(b) "CND" means the Child Nutrition Division of the Food and Service of the U.S. Department of Agriculture.

(n) "SAE" means federally provided State administrative expense funds for State agencies under this part.

§235.4 [Amended]

4. In § 235.4, paragraphs (c), (d), and (e) are removed, and paragraphs (f), (g), and (h) are redesignated (c), (d), and (e) respectively.

5. Section 235.5 is revised to read as follows:

§ 235.5 Payment to States.

(a) Method of payment. FNS will specify the terms and conditions of the State agency's annual grant of SAE funds in conjunction with the grant award document and will make funds available for payment by means of a Letter of Credit issued in favor of the State agency. The total amount of a State agency's grant shall be equal to the sum of the amounts allocated to such agency under § 235.4 plus or minus any adjustments resulting from the reallocation provisions under paragraph (d) of this section plus any transfers under § 235.6(a) and/or § 235.6(c) of this part. The amount of SAE funds made available for payment to a State agency in any fiscal year shall be determined by FNS upon approval of the State agency's administrative plan for the fiscal year under paragraph (b) of this section and any amendments to such plan under paragraph (c) of this section. Funds shall not be made available before the State agency's plan or amendment to such plan, as applicable, has been approved by FNS. However, if the plan has not been approved by October 1 of the fiscal year, FNS may advance SAE funds to the State agency, in amounts determined appropriate by FNS, pending approval of the plan.

(b) Administrative plan. (1) Based on guidance provided by FNS, each State agency shall submit to FNS, by August 15 of each year, a plan for meeting its administrative responsibilities under the National School Lunch Program, School Breakfast Program, Special Milk Program, Child Care Food Program, and

Food Distribution Program in schools and child care institutions as applicable, for the upcoming fiscal year; except that, for the fiscal year beginning October 1, 1986, such plan shall be due by September 2, 1986. If FNS determines that a State agency is unable to comply with a due date under this subparagraph, it may grant an extension to the State agency.

- (2) The State agency's plan shall include its staffing pattern for State level personnel; a budget for the forthcoming fiscal year showing projected amounts (combined SAE and State funds) by cost category; the total amount of budgeted funds to be provided from State sources; the total amount of budgeted funds to be provided under this part; the State agency's estimate of the total SAE carryover from the current fiscal year; the State agency's estimate of the total amount of budgeted funds (combined SAE and State funds) attributable to administration of the School Nutrition Programs (National School Lunch, School Breakfast and Special Milk Programs), Child Care Food Program, and/or Food Distribution Program in schools and child care institutions and to each of the major activity areas of the State agency; and the State agency's estimate of the total Child Care Food Program two percent audit funds to be used for the forthcoming fiscal year. These activity areas shall be defined and described by the State agency in accordance with guidance issued by FNS and may include such activities as program monitoring, technical assistance, Federal reporting/claims processing, policy implementation, and allocation of foods to recipient agencies
- (3) The basic guidance issued by FNS for preparation of the plan shall provide flexibility in reporting with a minimal amount of reporting burden for State agencies. Such guidance, however, may be expanded for individual State agencies in order to address specific administrative deficiencies which affect compliance with program requirements and which have been identified by FNS through management evaluations, audits or other means. Except in specific instances where determined necessary by FNS, State agencies shall not be required to maintain expenditure records by activity area or program. State agencies shall refer to Office of Management and Budget Circular A-87, Attachment B to establish cost categories. In accordance with Office of Management and Budget Circular A-102, Attachment F, State agency plans for the forthcoming fiscal year shall include not only the projected expenditures of State

Reallocation Report (FNS-525) on the

funds by the State agency (as required above), but also all projected expenditures of State funds by other divisions of the State that will be applied to the State funding requirement under § 235.11(a) of this part.

(4) FNS shall approve a State agency's plan, or any amendment to such plan under paragraph (c) of this section, if it determines that the plan or amendment is consistent with program administrative needs and SAE requirements under this part. In approving a State agency's administrative plan or amendment thereto, FNS shall determine the amount of SAE funds to be made available for payment to the State agency. For any fiscal year, this amount shall be based on the amount of SAE funds justified in the administrative plan as amended, but shall not exceed the total of the following: SAE funds allocated to the State agency under § 235.4 of this part for the fiscal year, any SAE funds carried over from the prior fiscal year grant, any SAE funds transferred to the State agency by another State agency within the State under § 235.6(a) and/or § 235.6(c) of this part and any SAE funds reallocated to the State agency under paragraph (d) of this section.

(5) To the extent practicable, State agencies shall implement their approved plans (as amended). FNS shall monitor State agency implementation of the plans through management evaluations. State agency reports submitted under this part, and through other available

(c) Amendments to the administrative plan. A State agency may amend its administrative plan at any time during the fiscal year to justify the need for additional SAE funds up to the limit specified in paragraph (b) of this section. Any such amendment shall provide information in a format consistent with that provided in the State agency's plan under paragraph (b) of this section and must be approved by FNS before additional SAE funds are made available for payment to the State agency. In accordance with guidance provided by FNS, a State agency shall also amend its administrative plan to reflect other changes in funding or funding needs. An amendment of this type shall also provide information in a format consistent with that provided in the State agency's plan, but shall only require FNS approval if it results in a significant reduction in funding level or

level of planned activity.
(d) Reallocation of funds. Annually, between March 1 and May 1 on a date specified by FNS, of each year, each State agency shall submit to FNS a State Administrative Expense Funds

use of SAE funds. At such time, a State agency may release to FNS any funds that have been allocated, reallocated or transferred to it under this part or may request additional funds in excess of its current grant level. Based on this information or on other available information, FNS shall reallocate, as it determines appropriate, any funds allocated to State agencies in the current fiscal year which will not be expended in the following fiscal year and any funds carried over from the prior fiscal year which will not be expended in the current fiscal year. Reallocated funds shall be made available for payment to a State agency upon approval by FNS of the State agency's plan under this section and an amendment to such plan which covers the reallocated funds. Notwithstanding any other provision of this part, a State agency may, at any time, release to FNS for reallocation any funds that have been allocated, reallocated or transferred to it under this part and are not needed to implement its approved plan under this section. (e) Return of funds. Each State agency

shall return to FNS any funds made available through its Letter of Credit under this part which are unexpended at the end of the fiscal year following the year for which such funds were originally allocated. Return of funds by the State agency shall be made as soon as practicable, but in any event, not later than 30 days following demand by

FNS.

§ 235.6 [Amended]

6. In § 235.6:

A. Paragraphs (a) and (a-1) are redesignated as (a-1) and (a-2) respectively, and a new paragraph (a) is added to read as follows:

b. The words "Federal Management Circular 74-4 (32 CFR Part 255)" in paragraph (b) are changed to read "Office of Management and Budget Circular A-87".

c. The last sentence of paragraph (c) is

The addition specified above reads as follows:

§ 235.6 Use of funds.

(a) Funds allocated under this part and 7 CFR Part 225 shall be used for State agency administrative costs incurred in connection with the programs governed by 7 CFR Parts 210, 215, 220, 225, 226, and 250 of this title. Except as provided under § 235.6(c). funds allocated under § 235.4, paragraphs (a) and (b) and 7 CFR Part 225 shall be used for the program(s) for which allocated, except that the State

agency may transfer up to ten percent of the funds allocated for any such program(s) to other such program(s). Subject to the provisions of this paragraph, a State agency may also transfer SAE funds that are not needed to implement its approved plan § 235.5(b) to another State agency within the State that is eligible to receive SAE funds under this part. Funds for any fiscal year which are allocated, reallocated or transferred to a State agency under this part shall, subject to the provisions of § 235.5 of this part, remain available for obligation and expenditure by such State agency during the following fiscal year.

7. In § 235.7, paragraph (b) is amended by adding a sentence between the fifth and sixth sentences to read as follows:

§ 235.7 Reports and reports. 10

(b) * * * Based on guidance provided by FNS, each State agency shall also use the quarterly SF-269 to report on the use of State funds provided during the fiscal year. * * *

8. In § 235.11, paragraph (a) is amended by adding a sentence to the end of the paragraph to read as follows:

§ 235.11 Other provisions.

(a) * * * State agencies shall follow, as applicable, the provisions of Office of Management and Budget Circular A-102, Attachments F and G and 7 CFR Part 3015, Subparts G and H in identifying and documenting expenditures of funds from State revenues to meet the State funding requirement of this paragraph.

Dated: July 25, 1986.

Robert E. Leard, Administrator.

[FR Doc. 86-17197 Filed 7-29-86; 8:45 am] BILLING CODE 3410-30-M

Agricultural Marketing Service

7 CFR Parts 1030, 1032, 1033, 1036, 1049, and 1050

[Docket Nos. AO-351-A24, et al.]

Milk in the Chicago Regional and Certain Other Marketing Areas; Interim **Amendment of Orders**

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule.

SUMMARY: This action modifies on an interim basis the plant location adjustments to prices under the

Southern Illinois, Ohio Valley, Indiana, and Central Illinois milk orders based on industry proposals considered at a public hearing held March 12–14, 1986. The location adjustment provisions of the four orders are amended in order to conform with the higher Class I differentials mandated by the Food Security Act of 1985. In several orders, changes are also needed to assure the proper intra-market alignment of prices. More than two-thirds of the producers in each of the four markets have approved the interim amendments to the order for their market.

The hearing in this proceeding reopened an earlier proceeding on proposed amendments to change the location adjustment provisions of the Eastern Ohio-Western Pennsylvania order. A separate document will deal with the Eastern Ohio-Western Pennsylvania order and the issues related thereto.

This action does not adopt any change for the Chicago Regional milk order in that all relevant proposals were withdrawn at the hearing.

EFFECTIVE DATE: August 1, 1986.

FOR FURTHER INFORMATION CONTACT:

Maurice M. Martin, Marketing Specialist, Dairy Division, Agricultural Marketing Service, United States Department of Agriculture, Washington, DC 20250, (202) 447–7311.

SUPPLEMENTARY INFORMATION: This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Order 12291.

Prior documents in this proceeding: Notice of Hearing: Issued February 14, 1986; published February 21, 1986 (51 FR 6241).

Interim Final Decision: Issued June 26, 1986; published July 8, 1986 (51 FR 24677).

Findings and Determinations

The findings and determinations hereinafter set forth supplement those that were made when the aforesaid orders were first issued and when they were amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) Findings upon the basis of the hearing record. Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon certain proposed amendments to the tentative

marketing agreements and to the orders regulating the handling of milk in the respective marketing areas.

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

- (1) The said orders as hereby amended on an interim basis, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act:
- (2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the said marketing areas; and the minimum prices specified in the orders as hereby amended on an interim basis, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and
- (3) The said orders as hereby amended on an interim basis regulate the handling of milk in the same manner as marketing agreements upon which a hearing has been held. The said orders as hereby amended on an interim basis are applicable only to persons in the respective classes of industrial or commercial activity specified in the same marketing agreements

(b) Additional findings. It is necessary in the public interest to make these interim amendments to each of the aforesaid orders effective August 1, 1986. Any delay beyond that date would tend to disrupt the orderly marketing of milk in the marketing areas.

The interim amendments to these orders are known to handlers. The interim final decision of the Deputy Assistant Secretary containing all interim amendments to these orders was issued June 26, 1986 (51 FR 24677). The changes effected by these interim amendments will not require extensive preparation; nor will there be substantial alteration in method of operation for handlers. In view of the foregoing, it is hereby found and determined that good cause exists for making these interim amendments to each of the aforesaid orders effective August 1, 1986, and that it would be contrary to the public interest to delay the effective date of these amendments for 30 days after publication in the Federal Register. (Section 553(d), Administrative Procedure Act, 5 U.S.C. 551-559).

- (c) Determinations. It is hereby determined that:
- (1) The refusal or failure of handlers (excluding cooperative associations specified in section 8c (9) of the Act) of more than 50 percent of the milk, which

is marketed within each of the respective marketing areas, to sign a proposed marketing agreement, tends to prevent the effectuation of the declared policy of the Act;

(2) The issuance of these interim amendments to each of the specified orders is the only practical means pursuant to the declared policy of the Act of advancing the interests of producers as defined in the respective orders; and

(3) The issuance of these interim amendments to each of the specified orders is approved by more than the necessary two-thirds of the producers who during the determined representative period were engaged in the production of milk for sale in the marketing area.

List of Subjects in 7 CFR Parts 1032, 1033, 1049, and 1050

Milk marketing order, Milk, Dairy products.

Order Relative to Handling

It is therefore ordered, That on and after the effective date hereof, the handling of milk in each of the specified marketing areas shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as amended, and as hereby further amended, as follows:

The authority citation for 7 CFR Parts 1032, 1033, 1049, and 1050 continues to read as follows:

Authority: Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

PART 1030-MILK IN THE CHICAGO REGIONAL MARKETING AREA

Note.-No amendatory action taken.

PART 1032—MILK IN THE SOUTHERN ILLINOIS MARKETING AREA

1. Section 1032.52 is amended by revising paragraphs (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), (b) and adding (a)(2)(iii) to read as follows:

§ 1032.52 Plant location adjustments for handlers.

(a) * * *

(1) For a plant located within one of the zones designated in § 1032.2, the adjustment shall be as follows:

Zone	Adjustment per hundredweight
Base Zone	No
Northern Zone	adjustment. Minus 17
Southern Zone	cents. Plus 9 cents.

2) * * *

(i) Plus 9 cents. St. Clair County (Scott Military Reservation, East St. Louis, Centreville, Canteen, and Stites Townships and the city of Belleville only) in the State of Illinois and the counties of Jefferson, St. Charles and St. Louis and the city of St. Louis in the State of Missouri.

- (ii) Minus 17 cents. In the counties of Fountain, Parke, Vermillion and Warren in the State of Indiana.
- (iii) No location adjustment shall apply at a plant located in the State of Missouri south and east of Interstate Highway 44 that was not in an area described in paragraph (a)(2)(i) of this section.
- (3) For a plant located outside the marketing area and the area described in paragraph (a)(2) of this section, the adjustment shall be minus 20 cents for any such plant located 100 miles or more from the city or village limit of Alton, Robinson, or Vandalia, Illinois, whichever is nearest, and minus additional 2.0 cents for each 10 miles or fraction thereof that such distance exceeds 110 miles.
- (4) In determining location adjustments pursuant to this section, mileage shall be based on the shortest hard-surfaced highway distance as determined by the market administrator from the latest Mileage Guide as published by the Household Goods Carrier's Bureau.
- (b) For purposes of calculating such adjustment, bulk transfers between pool plants shall be assigned Class I disposition at the transferee-plant only to the extent that 110 percent of Class I disposition at the transferee-plant exceeds the sum of receipts at such plant from producers and handlers described in § 1032.9(c), and the volume assigned as Class I to receipts from other order plants and unregulated supply plants, such assignment to be made first to receipts of fluid milk products from pool plants at which no location adjustment credit is applicable and then in sequence beginning with the plant at which the least location adjustment would apply.

PART 1033—MILK IN THE OHIO VALLEY MARKETING AREA

1. Section 1033.6 is amended by revising paragraphs (a), (b), (c), and adding (d) and (e) to read as follows:

§ 1033.6 Ohio Valley marketing area.

(a) "Zone 1" shall include the following territory:

Ohio Counties

Fulton, Hancock, Henry, Lucas, Putnam, Sandusky (Woodville and Madison Townships only), Seneca, Wood.

Michigan Counties

Lenawee (Blissfield, Deerfield, Ogden, Palmyra, and Riga Townships only). Monroe (except Ash, Berlin, Dundee, Exeter, London, and Milan Townships).

(b) "Zone 2" shall include the following territory:

Ohio Counties

Allen Auglaize, Crawford, Darke, Hardin, Logan, Marion, Mercer, Morrow, Richland, Shelby, Union, Van Wert (city of Delphos only), Wyandot.

(c) "Zone 3" shall include the following territory:

Ohio Counties

Butler, Champaign, Clark, Clinton, Coshocton (except Adams Township), Delaware, Fairfield, Fayette, Franklin, Greene, Guernsey (except Oxford, Londonderry, and Millwood Townships), Hocking, Knox, Licking, Madison, Miami, Montgomery, Morgan, Muskingum, Noble, Perry, Pickaway, Preble, Warren.

(d) "Zone 4" shall include the following territory:

Ohio Counties

Adams, Athens, Brown, Clermont, Gallia, Hamilton, Highland, Jackson, Lawrence, Meigs, Pike, Ross, Scioto, Vinton, Washington.

Kentucky Counties

Boone, Boyd, Bracken, Campbell, Grant, Greenup, Harrison, Kenton, Lewis, Mason, Pendleton, Robertson.

Indiana Counties

Dearborn, Ohio.

West Virginia Counties

Calhoun, Gilmer, Pleasants, Ritchie, Wirt, Wood.

(e) "Zone 5" shall include the following territory:

Kentucky Counties

Floyd, Johnson, Laurence, Magoffin, Martin, Pike.

West Virginia Counties

Boone, Cabell, Fayette, Jackson, Kanawha, Lincoln, Logan, Mason, Mingo, Putnam, Raleigh, Roane, Wayne, Wyoming.

2. Section 1033.53 is amended by revising paragraphs (a)(1), (a)(2), (a)(3), redesignating (a)(4) as (a)(5), and adding (a)(4) to read as follows:

§ 1033.53 Plant location adjustments for handlers.

- (a) * * *
- (1) At a plant located in one of the zones set forth in § 1033.6, the adjustment shall be as follows:

Zone	Adjustment per hundredweight
1	cents. Minus 14
3	cents. No adjustment.
4 5	Plus 7 cents. Plus 15 cents.

- (2) At a plant located outside the marketing area and 60 miles or less from the city hall of the nearest city listed herein, excluding plants located in the area specified in (a)(4) of this section, the adjustment shall be the adjustment applicable at Cincinnati, Coshocton, Dayton, Lima, Marietta, or Toledo, Ohio; Ashland or Maysville, Kentucky; or Beckley or Charleston, West Virginia; whichever city is nearest;
- (3) At a plant located outside the marketing area and more than 60 miles from the city hall of the nearest city listed in paragraph (a)(2) of this section, excluding plants located in the area specified in (a)(4) of this section, the adjustment shall be the adjustment applicable at the nearest city, less 11 cents and less an additional 1.5 cents for each 10 miles or fraction thereof in excess of 70 miles that such plant is located from the city hall of the nearest city listed above. However, at any such plant located in the Lousiville-Lexington-Evansville marketing area under Part 1046 of this chapter or east of the Mississippi River and south of the northern boundary of Kentucky, West Virginia, or Virginia, the adjustment shall be the adjustment applicable at Zone 4:
- (4) At a plant located outside the marketing area in the Ohio counties of Defiance, Paulding, Van Wert, (except the city of Delphos), or Williams, the adjustment shall be minus 24 cents; and
- (5) For the purpose of computing location adjustments pursuant to this section, distances shall be measured by the shortest hard-surfaced highway distance as determined by the market administrator.

PART 1036—MILK IN THE EASTERN OHIO-WESTERN PENNSYLVANIA MARKETING AREA

Note.—A separate document will be issued regarding the issues related thereto.

PART 1049—MILK IN THE INDIANA MARKETING AREA

1. In § 1049.52, paragraphs (a)(1) and (a)(2) are revised to read as follows:

§ 1049.52 Plant location adjustments for handlers.

(a) * * *

(1) At any plant located within:

	Rate of adjust- ment per hundred- weight (cents)
(i) The State of Ohio or any Indiana county not specifically named in paragraph (a)(1)(ii) through (a)(1)(iv) of this section or at any location south of the marketing area as speci-	
fied in § 1049.2	0
tington, Jay, Miami, Wabash, Wells, and White (iii) Any of the Indiana counties of: DeKalb, Elkhart, Jasper, Kosciusko, Lagrange, La Porte, Marshall, Newton, Noble, Pulaski, Starke, Steuben, St. Joseph, and Whitley and any of the Michigan counties of Berrien,	20
Branch, Cass, and St. Joseph	30
Porter	40

(2) For any plant at a location outside the territory specified in the preceding paragraph (a)(1) of this section, the applicable adjustment rate per hundredweight shall be based on the shortest highway distance between the plant and the nearest of the Monument Circle, Indianapolis, Indiana, or the main post offices of Fort Wayne, South Bend, or Valparaiso, Indiana, and shall be 2.0 cents for each 10 miles or fraction thereof from such point plus the amount of the location adjustment pursuant to paragraph (a)(1) of this section applicable at the respective point.

PART 1050—MILK IN THE CENTRAL ILLINOIS MARKETING AREA

1. In § 1050.52, paragraphs (a) and (b) are revised to read as follows:

§ 1050.52 Plant location adjustments for handlers.

(a) The Class I price for producer milk at a plant located outside the State of Illinois or in the State of Illinois but north of the northernmost boundaries of the counties of Mercer, Henry, Bureau, La Salle, Grundy, and Kankakee shall be reduced 10 cents if such plant is 50 miles or more from the City Hall in Peoria, Illinois, plus an additional 2.0 cents for each 10 miles or fraction thereof that such distance exceeds 60 miles. Distances applied pursuant to this paragraph shall be the shortest hardsurfaced highway distances as determined by the market administrator from the latest Mileage Guide as published by the Household Goods Carrier's Bureau.

(b) For purposes of calculating such adjustment, bulk transfers between pool plants shall be assigned Class I disposition at the transferee-plant only to the extent that 105 percent of Class I disposition at the transferre-plant exceeds the sum of receipts at such plant from producers and cooperative associations pursuant to § 1050.9(c), and the volume assigned as Class I to receipts from other order plants and unregulated supply plants; such assignment to be made first to transferor-plants at which no location adjustment credit is applicable and then in sequence beginning with the plant at which the least location adjustment would apply.

Effective date: August 1, 1986.

Signed at Washington, DC, on: July 24, 1986.

Karen K. Darling,

Deputy Assistant Secretary, Marketing & Inspection Services.

[FR Doc. 86-17050 Filed 7-29-86; 8:45 am] BILLING CODE 3410-02-M

7 CFR Part 1076

Milk in the Eastern South Dakota Marketing Area; Order Suspending Certain Provisions

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Suspension of rule.

SUMMARY: This action suspends for the months of August 1986 through February 1987 certain provisions of the Eastern South Dakota milk order. The provisions suspended relate to the amount of milk not needed for fluid (bottling) use that may be moved directly from farms to nonpool manufacturing plants and still be priced under the order. Suspension of the provisions was requested by a cooperative association representing most of the producers supplying the market. The suspension is needed to prevent uneconomic movements of milk.

EFFECTIVE DATE: August 1, 1986.

FOR FURTHER INFORMATION CONTACT: Constance M. Brenner, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, DC 20250, [202] 447–7311.

SUPPLEMENTARY INFORMATION: Prior document in this proceeding:

Notice of Proposed Suspension: Issued June 18, 1986; published June 24, 1986 (51 FR 22944).

The Administrator of the Agricultural Marketing Service has certified that this action will not have a significant economic impact on a substantial number of small entities. This action lessens the regulatory impact of the order on certain milk handlers and tends

to ensure that dairy farmers will continue to have their milk priced under the order and thereby receive the benefits that accrue from such pricing.

This order of suspension is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and of the order regulating the handling of milk in the Eastern South Dakota marketing area.

Notice of proposed rulemaking was published in the Federal Register on June 24, 1986 (51 FR 22944) concerning a proposed suspension of certain provisions of the order. Interested persons were afforded opportunity to file written data, views, and arguments thereon.

After consideration of all relevant material, including the proposal in the notice, the comments received, and other available information, it is hereby found and determined that for the months of August 1986 through February 1987 the following provisions of the order do not tend to effectuate the declared policy of the Act:

In § 1076.13, paragraphs (c) (2) and (3)

Statement of Consideration

This action removes for the months of August 1986 through February 1987 the limit on the amount of producer milk that a cooperative association or other handle may divert from pool plants to nonpool plants. The suspension was requested by Land O'Lakes, Inc. (LOL), an association of producers that supplies most of the market's reserve milk supplies.

The order now provides that a cooperative association may divert up to 35 percent of its total member milk received at all pool plants or diverted therefrom during the months of August through February. Similarly, the operator of a pool plant may divert up to 35 percent of its receipts of producer milk (for which the operator of such plant is the handler during the month) during the months of August through February.

The suspension is necessary to assure the continued participation in the marketwide pool of producers historically associated with the Eastern South Dakota market. Operation of the 35-percent diversion limit during August through February would require LOL to deliver 65 percent of its milk to pool plants. According to the cooperative's estimates, only 36 to 46 percent of its milk will be needed at distributing plants. Without suspension of the diversion limit, the balance of LOL's members' milk would have to be delivered to a supply plant, unloaded,

reloaded and then shipped to other plants merely to qualify the milk for pooling. The additional handling and hauling costs would be incurred by LOL and its member producers, with no offsetting benefits to other market participants.

In comments filed in support of the proposed suspension, LOL stated that requiring the full 65 percent of its milk to be delivered to pool plants would serve no useful purpose other than demonstrating the availability of a reserve supply of milk for Class I use. The cooperative argued that because the reserve milk will not be needed for Class I use, the requirement should be suspended.

In view of these circumstances, it is concluded that the diversion limits in the Eastern South Dakota milk order should be suspended for the months of August 1986 through February 1987 to ensure the orderly marketing of milk supplies. The suspension will prevent uneconomic movements of some milk through pool plants merely for the purpose of qualifying it for producer milk status under the order.

It is hereby found and determined that thirty days' notice of the effective date hereof is impractical, unnecessary and contrary to the public interest in that:

- (a) The suspension is necessary to reflect current marketing conditions and to assure orderly marketing conditions in the marketing area in that without extensive unnecessary and expensive hauling and handling substantial quantities of milk from producers who regularly supply the market otherwise would be excluded from the marketwide pool, thereby causing a disruption in the orderly marketing of milk;
- (b) This suspension does not require of persons affected substantial or extensive preparation prior to the effective date; and
- (c) Notice of proposed rulemaking was given interested parties and they were afforded opportunity to file written data, views or arguments concerning this suspension. No comments were filed in opposition to this action.

Therefore, good cause exists for making this order effective upon publication in the Federal Register.

List of Subjects in 7 CFR Part 1076

Milk marketing orders, Milk, Dairy products.

It is therefore ordered, That the aforesaid provisions of § 1076.13 of the Eastern South Dakota order are hereby suspended for the months of August 1986 through February 1987, as follows:

PART 1076—MILK IN THE EASTERN SOUTH DAKOTA MARKETING AREA

1. The authority citation for Part 1076 continues to read as follows:

Authority: Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

§ 1076.13 [Amended]

2. In § 1076.13, paragraphs (c) (2) and (3) are suspended for the months of August 1986 through February 1987. Effective Date: August 1, 1986.

Signed at Washington, DC, on: July 24, 1986.

Karen K. Darling,

Deputy Assistant Secretary, Marketing & Inspection Services.

[FR Doc. 86–17051 Filed 7–29–86; 8:45 am] BILLING CODE 3410-02-M

Farmers Home Administration

7 CFR Part 1944

Revision of Section 502 Rural Housing Loan Policies, Procedures and Authorizations

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends its regulations regarding Section 502 rural housing (RH) loans to authorize the delivery of Form FmHA 1910-5, "Request for Verification of Employment," to the contractor's office address rather than to the FmHA County Office address for those RH borrowers whose annual interest credit renewals (ICRs) are done by a contractor. The circumstance requiring this action is the need for contractors to be able to meet submission deadlines on ICR packages. FmHA regulations formerly required all Forms FmHA 1910-5 to be returned only to the FmHA County Office. The intended effect is to speed up the contractor's submission of completed ICRs for the County Supervisor's approval within the allotted time frame.

EFFECTIVE DATE: July 30, 1986.

FOR FURTHER INFORMATION CONTACT: Frank Colon, Branch Chief, Home Ownership, Single Family Housing Processing Division, Farmers Home Administration, USDA, Room 5334, South Agriculture Building, 14th and Independence Avenue SW., Washington, DC 20250. Telephone (202)

382-1474.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established in Departmental

Regulation 1512–1 which implements Executive Order 12291, and has been determined to be exempt from those requirements because it involves only internal Agency management. It is the policy of this Department to publish for comment rules relating to public property, loans, grants, benefits, or contracts notwithstanding the exemption in 5 U.S.C. 553 with respect to such rules. This action, however, is not published for proposed rulemaking, since it involves only internal Agency management and publication for comment is unnecessary.

FmHA Section 502 rural housing regulations previously required Form FmHA 1910-5 to be returned only to the County Supervisor from the employer when income was being verified for program assistance. Applicants/ borrowers and application packagers were not included in the routing of the completed form in order to protect the accuracy of the information provided by the employer. However, on July 3, 1985, FmHA State Directors were given the authority, with prior approval by the Administrator, to enter into contracts for the processing of ICRs. Contractors are to be responsible for the annual ICR except for approval of the completed Interest Credit Agreement. They are to pick up the renewal packets at the FmHA County Office and deliver completed ICRs back to the County Supervisor within a specified, rather short time span of 21/2 months. In order to expedite this process and eliminate either forwarding of the Forms FmHA 1910-5 by the County Supervisor or burdensome trips to retrieve them by the contractors, we are amending our regulations to specify that Form FmHA 1910-5 may be mailed by the employer directly to the contractor, if applicable.

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.410. For the reasons set forth in the Final Rule related Notice to 7 CFR Part 3015, Subpart V, 48 FR 29115, June 24, 1983, this program/activity is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

This document has been reviewed in accordance with 7 CFR Part 1940, Subpart G, "Environmental Program." It is the determination of FmHA that this action does not constitute a major Federal action significantly affecting the quality of the human environment and in accordance with the National Environmental Policy Act of 1969, Pub. L. 91–190, an Environmental Impact Statement is not required.

List of Subjects in 7 CFR Part 1944

Home improvement, Loan programs— Housing and community development, Low and moderate income housing— Rental, Mortgages, Rural housing, Subsidies.

For the reasons set out in the preamble, Chapter XVIII, Title 7 of the Code of Federal Regulations is amended as follows:

PART 1944-HOUSING

1. The authority citation for Part 1944 continues to read as follows:

Authority: 42 U.S.C. 1480; 7 CFR 2.23; 7 CFR 2.70.

Subpart A—Section 502 Rural Housing Loan Policies, Procedures, and Authorizations

2. Section 1944.26 is amended by adding paragraph (a)(5) to read as follows:

§ 1944.26 Application processing.

(a) * * *

(5) Form 1910-5, "Request for Verification of Employment," will be used to verify employment or income of the loan applicant. The form will be mailed or hand-carried to the employer only by the FmHA authorized representative (e.g., FmHA employee, contractor for interest credit renewals, or contractor for account servicing actions), authorized packagers for rural housing applications, or in the case of interest credit renewals, by the borrower. When FmHA mails the form directly to the employer, the Agency will provide self-addressed "Business Reply Mail" envelope(s) for the employer to return the completed form to FmHA. In all other cases, the sender will provide the employer with stamped envelopes for returning the completed form. The envelopes provided to the employer will be pre-addressed with the County Office address except in the case of contractors for interest credit renewals or contractors for other servicing actions where their return addresses will be shown. Other income information that cannot be obtained by the use of this form, may be obtained by mail from the other sources of income. * * *

3. Section 1944.34 is amended by revising paragraphs (h)(3)(i) and (h)(3)(ii) to read as follows:

§ 1944.34 Interest credit.

(h) * * * (3) * * *

(i) Initiation of renewal action. At the beginning of the annual review period, the Finance Office will mail to the County Office a list of borrowers whose Interest Credit Agreements are to be reviewed, together with a package to be mailed by the County Supervisor to each borrower or to be picked up at the County Office by the contractor for interest credit renewals. The package will contain Form FmHA 1944–A6 (3 parts with carbon interleaved). If the renewal Form 1944–A6 is for the first year review period following the effective date of the agreement, it will contain the following legend:

"Subsidy for (ensuing year) of \$_____. Is this correct? |

The County Supervisor or the contractor will complete Form FmHA 1944-1, "Interest Credit Agreement Renewal," according to the FMI for the form and insert it in the package together with two Forms FmHA 1910-5. Two envelopes which have been preaddressed with the County Office address or the address of the contractor, if applicable, will be inserted in the package to be used by the employer(s) to mail the Verification of Employment form(s) to the County Office or to the contractor. Postage for these envelopes will be provided as set forth in § 1944.26 (a)(5) of this subpart.

(ii) Borrower responsibility. Upon receipt of the package, the borrower will give one copy of the Verification of Employment form to the employer or employers of each member of the household who has income to be considered. A stamped envelope will be provided each employer to facilitate the mailing of the Verification of Employment form directly to the County Office or to the contractor, if applicable. The borrower will also complete part II of the Interest Credit Agreement from (leaving carbon intact), sign the original form and bring the original and all copies to the County Office or to the office of the contractor.

Dated: July 1, 1986.

Dwight O. Calhoun, Acting Administrator, Farmers Home Administration.

[FR Doc. 86-17123 Filed 7-29-86; 8:45 am] BILLING CODE 3410-07-M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 238

Contracts With Transportation Lines; Addition of ANA All Nippon Airways

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

(202) 633-3048.

SUMMARY: This rule adds ANA All Nippon Airways to the list of carriers which have entered into agreements with the Service to guarantee the passage through the United States in immediate and continuous transit of aliens destined to foreign countries.

EFFECTIVE DATE: June 13, 1986.

FOR FURTHER INFORMATION CONTACT: Loretta J. Shogren, Director, Policy Directives and Instructions, Immigration and Naturalization Service, 425 I Street, NW., Washington, DC 20536, Telephone:

SUPPLEMENTARY INFORMATION: The Commissioner of Immigration and Naturalization entered into an agreement with ANA All Nippon Airways on June 13, 1986 to guarantee passage through the United States in immediate and continuous transit of aliens destined to foreign countries.

The agreement provides for the waiver of certain documentary requirements and facilitates the air travel of passengers on international flights while passing through the United States.

Compliance with 5 U.S.C. 553 as to notice of proposed rulemaking and delayed effective date is unnecessary because the amendment merely makes an editorial change to the listing of transportation lines.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization certifies that the rule will not have a significant impact on a substantial number of small entities.

This order constitutes a notice to the public under 5 U.S.C. 552 and is not a rule within the definition of section 1(a) of E.O. 12291.

List of Subjects in 8 CFR Part 238

Airlines, Aliens, Government contracts, Travel, Travel restriction.

Accordingly, Chapter I of Title 8 of the Code of Federal Regulations is amended as follows:

PART 238—CONTRACTS WITH TRANSPORTATION LINES

The authority citation for Part 238 continues to read as follows:

Authority: Secs. 103 and 238 of the Immigration and Nationality Act, as amended (8 U.S.C. 1103 and 1228).

§ 238.3 [Amended]

2. In § 238.3 Aliens in immediate and continuous transit, the listing of transportation lines in paragraph (b) Signatory lines is amended by: Adding

in alphabetical sequence, ANA All Nippon Airways.

Dated: June 19, 1986. Richard E. Norton,

Associate Commissioner, Examinations, Immigration and Naturalization Service [FR Doc. 86-17045 Filed 7-29-86; 8:45 ani]

BILLING CODE 4410-10-M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2 and 60

Disposal of High-Level Radioactive Wastes in Geologic Repositories: Amendments to Licensing Procedures

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations applicable to the disposal of high-level radioactive wastes in geologic repositories. These amendments deal with procedural aspects of site characterization and the participation of States and Indian Tribes. Among other things, the rules set forth requirements applicable to the Department of Energy for submitting site characterization plans. For the most part, the amendments to licensing procedures are changes made to reflect the provisions of the Nuclear Waste Policy Act of 1982

EFFECTIVE DATE: August 29, 1986.

FOR FURTHER INFORMATION CONTACT: Clark Prichard, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 427-4586.

SUPPLEMENTARY INFORMATION:

Background

On February 25, 1981, the Nuclear Regulatory Commission (NRC) promulgated licensing procedures for the disposal of high-level radioactive waste (HLW) in geologic repositories (46 FR 13971). The enactment of the Nuclear Waste Policy Act of 1982 (NWPA), 42 U.S.C. 10101 et seq., brought about a need to revise some of the procedures in 10 CFR 60. The NWPA set forth in considerable detail the procedures to be followed during the process of siting and development of HLW geologic repositories, and the respective roles of NRC, the Department of Energy (DDE), and States and Indian Tribes. These amendments contain the changes to 10 CFR Part 60 that are needed to conform the licensing procedures in the rule to the provisions of the NWPA. In addition, the amendments contain some changes considered desirable in light of experience gained with the pre-licensing consultation process since the promulgation of the procedural part of 10 CFR Part 60.

On January 17, 1985 the Commission published proposed procedural amendments to 10 CFR Part 60 for public comment (50 FR 2579). The proposed amendments contained revisions to (1) the content of the site characterization plan (SCP), (2) NRC review of the SCP, and the issuance by NRC of a site characterization analysis (SCA), (3) means and timing of State and Indian Tribe consultation with NRC and participation in NRC reviews, and (4) notice and publication by NRC with respect to site characterization documents. The Commission received a number of comments on the proposed amendments, all of which have been carefully considered. The principal issues raised by these comments are discussed below.

Comments

A total of 15 organizations commented on the proposed rule, addressing a variety of concerns. Five of these issues call for extended response in this statement. These issues are: whether NRC should issue a draft site characterization analysis; the deletion of site selection information from the contents of the SCP; whether DOE should be required to receive and consider comments on the SCP before starting to sink a shaft; whether all amendments of 10 CFR Part 60 and Part 51 to conform with the Nuclear Waste Policy Act, especially those related to NEPA requirements and the present amendments, should be promulgated at the same time; and whether host States should automatically be afforded party status in licensing proceedings. Summaries of the comments received on these issues are presented below. Copies of all the comments, and the Commission's analysis of them, are available in the Commission's Public Document Room.

a. Draft Site Characterization Analysis

There were several comments about the deletion of the draft site characterization analysis (SCA). Under the proposed rule, the NRC would have issued an SCA, a final set of comments on DOE's SCP, and would have invited public comment on its SCA for consideration in the ongoing staff review and commentary on the DOE program but would not have issued both a draft and a final SCA. Some commenters agreed with elimination of the draft SCA. However, most

commenters requested that NRC continue to issue its analysis in both a draft and final form. Commenting States and Tribes believe that they have substantial expertise which NRC should consider in preparing its analysis on the DOE SCP. Some States wanted to see NRC's draft SCA to have the benefit of NRC's expertise while preparing their own comments. Some commenters emphasized a belief that any schedule delays resulting from issuing a draft SCA would not be important. Some commenters believed that the opportunities and procedures for public and State involvement in the repository siting and development process under the NWPA are not substantially different from those contemplated when the previous regulations were promulgated. For this they concluded that there is no reason for NRC to change its procedures by eliminating the draft analysis on DOE's SCP's.

The Commission understands the concerns of the States, Tribes and public that their views be heard and considered. The Commission intends to be fully aware of State, Tribe and public views before, during, and after the site characterization plan review. The States and affected Indian Tribes will be routinely informed of the information made available to NRC and NRC's comments thereon. They are able to participate at NRC/DOE technical meetings. As is now being done, the NRC staff will continue to have discussions with State and affected Indian Tribe representatives and will respond to their written submissions. The NRC will also follow closely the NWPA mandated opportunities for State, Tribe and public interaction with DOE to be aware of the concerns which are expressed by the States and Tribes in these forums.

The need for opportunities for State.

Indian Tribe, and public involvement is addressed extensively by the NWPA. The procedures established by the statute provide means for informing NRC of issues of concern. Given these specific procedures, and taking into account the scheduling provisions of the NWPA, the publication of a draft SCA is no longer warranted. It is not required by law. It is important to note, however, that there will still be an opportunity to comment on NRC's SCA as the rule as amended requires the solicitation of such comments. NRC will make further comments to DOE if the State and public comments on NRC's SCA provide substantial new grounds for making recommendations or stating objections to DOE's site characterization program. (It should be noted, however, that NRC

does not contemplate a formal comment

analysis.)

To furnish additional assurance to the host State and affected Indian Tribes that their views will be considered in NRC's preparation of its SCA, a provision has been added to the final regulation providing an opportunity, before publication of the SCA by NRC, for those parties to present their views on the DOE SCP and suggestions with respect to NRC comments thereon.

b. Site Selection Information

Some commenters opposed the deletion of information concerning DOE's site screening and selection process from the SCP contents. Some commenters also commented unfavorably on a perceived lack of any NRC review of DOE's site screening and selection process. A few commenters supported the deletion of such information from the SCPs.

The Commission has carefully reviewed the arguments presented by the commenters who stated that site selection information should still be included in the SCPs. The Commission continues to believe that such information is neither appropriate nor

required in an SCP.

In regard to the generalized concern that NRC should be involved in the site selection process, it is noted that the NRC has played an important role in this process and will continue to do so. The sites under consideration for nomination have been the subject of continuous scrutiny by the NRC staff to identify licensing issues at the earliest possible stage. Available data are examined on a regular basis and site specific documents such as the environmental assessments are carefully reviewed. There are also activities specified by the NWPA which afford the NRC an opportunity to directly influence the site selection process. These are NRC concurrence in DOE's siting guidelines and review and comments on the site characterization plans. NRC expects that, under the EIS scoping process pursuant to CEQ rules, DOE will keep NRC fully and currently informed of its plans for implementation. We also expect to review and comment on DOE's scoping documents and activities for implementing NEPA in the repository program which are to be developed pursuant to CEQ rules, and to comment on DOE's EIS.

Thus, the issue of concern in this rulemaking is not whether the Commission should be involved in the DOE site screening and selection process generally. It is, more specifically, the scope of the information to be included in the DOE submission.

The NWPA, while generally conforming to the earlier NRC regulation, omitted the provisions dealing with NRC review of site selection matters. The Commission construes this action as an indication that the site selection issues previously dealt with in Part 60 were to be separated from the site characterization reports and dealt with. instead, in the environmental assessments. Under the NWPA, the Commission's role in the review of DOE's site characterization plans is to determine whether they are appropriate in light of the Commission's regulations. Attention will be directed toward the adequate of the characterization of a particular site; and this is different from, and not dependent upon, the considerations that led to the selection of that site.

c. Shaft Sinking

Some commenters suggested that the regulation should be amended to require that DOE may not proceed to characterize sites by sinking shafts until NRC and State review and comment upon the SCP are complete. One commenter suggested that the regulation be clarified to specify that completion of NRC review is not a condition precedent for shaft sinking. The Commission agrees with the commenters who regard NWPA as requiring that DOE defer the sinking of shafts at least until such time as there has been an opportunity for pertinent comments on shaft sinking to have been solicited and considered by DOE. As stated in the preamble to the proposed rule, "The Commission believes that Congress intended that DOE should provide the plans sufficiently far in advance so that comments may be developed and submitted back to DOE early enough to be considered when shaft sinking occurs, and all times thereafter." question, therefore, is not whether the Commission agrees with the objective of those commenters to defer shaft sinking until after comments on the SCP have been received by DOE. The issue, rather, was whether the Commission should include in its own regulations an interpretation of the obligations of DOE under the statute. The Commission has concluded that it should do so, in the interests of fulfilling its own responsibilities more effectively. The Commission has stressed the importance of evaluating alternatives to major design features that are important to waste isolation, see 10 CFR 60.21(c)(1)(ii)(D), and in the case of the design and location of the shafts this can only be done prior to their sinking. It is important to the Commission that the comments which it may provide to DOE

with respect to shaft sinking be taken into account as the Department proceeds.

The Commission observes that the incorporation of this language into the regulation should have no effect on the repository program. If the established working arrangements (including the Procedural Agreement, 48 FR 51876, described in the preamble to the proposed rule) provide the anticipated information exchange, NRC would in fact be able to review and comment in a timely fashion during DOE's early planning processes on those issues that may have a bearing upon DOE's decision to proceed with, or delay, the sinking of repository shafts. Moreover, the Commission is aware that DOE itself has indicated its intention to wait until it has completed a review of comments before proceeding to sink shafts.

d. Simultaneous Promulgation of Amendments

Some commenters recommended that all revisions to Part 60 and Part 51 to conform them to the NWPA should be promulgated simultaneously. In particular, they recommended that the revisions concerning NEPA requirements accompany the revisions currently being promulgated. They believe that this would assure that a comprehensive and integrated approach is taken and any confusion regarding NWPA and NEPA requirements would be eliminated. They argue that much of Part 60 now rests on NEPA authority so that failure to include NEPA in the currently proposed revision casts a cloud over the Commission's view of its authority to carry out early site reviews.

The Commission has not put off considering its obligations under NEPA as modified by the NWPA. In developing these changes to the regulation, the Commission has specifically considered whether any procedures might be needed at the site screening or characterization stage, so as to assure that the Commission would be able to meet its ultimate NEPA responsibilities. The Commission concludes that they are not.

The Commission's Part 51 regulations govern the Commission's responsibilities for conducting environmental reviews associated with its licensing and regulatory functions. Section 121(c) of NWPA, 42 U.S.C. 10141, clearly states that the requirements and criteria set forth in Part 60 relate to the Commission's responsibility under the Atomic Energy Act and the Energy Reorganization Act and do not require a NEPA EIS. The Part 51 changes, on the other hand, will

relate to the Commission's NEPA obligations at the time DOE applies for a license.

It appears that, under NWPA, NRC prelicensing review of NEPA issues was, in fact, not intended to be extensive. Aside from its concurrence in the siting guidelines, the statutory scheme calls for NRC participation to commence with the filing of the site characterization plans by DOE. Furthermore, unless DOE fails to follow the procedures for identifying sites to be characterized, as specified in NWPA, there would be no basis or authority to insist, for NEPA purposes, that particular sites be excluded or that other sites be selected for characterization.

It is important to proceed with the present actions without awaiting other changes to Part 51 that will be prepared in the light of the NWPA. This would allow for changes related to site characterization to be implemented in a timely fashion as DOE prepares its site characterization plans.

The Commission acknowledges that the authority citation for Part 60 includes a reference to NEPA; that is appropriate because the regulation specifies NEPA licensing findings, 10 CFR 60.31(c), 60.41(d), and contemplates the inclusion, in a construction authorization and a license, of conditions to protect environmental values, 10 CFR 60.32(a), 60.42(a). These sections, in essence, merely require that the construction and operation of a repository comply with NEPA requirements. They do not represent a reliance on NEPA authority as a significant underpinning for Part 60. Part 51 of NRC regulations, which deals with NEPA implementation, will however need to be changed-specifically to (1) define the alternatives that must be discussed in an environmental impact statement, (2) exempt the promulgation of NRC licensing requirements and criteria from environmental review under NEPA, and (3) set out procedures that will be followed by the Commission in determining whether or not to adopt the DOE EIS. The alternatives are, for the most part, prescribed by NWPA. The exemption of licensing requirements from environmental review is also an explicit feature of that Act. The procedures for adoption of the DOE environmental impact statement will be governed by NWPA and the regulations of the Council on Environmental Quality. These changes to Part 51 will be needed in order to conform NRC's licensing process to applicable law. Nothing in the present action impairs the Commission's ability to make the required changes to Part 51 or otherwise

to meet its NEPA obligations. Thus, in developing this current amendment the Commission has specifically considered whether any procedures might be needed during the current site screening process to assure meeting its ultimate NEPA responsibilities. The Commission concludes that they are not. Nothing in the upcoming Part 51 changes will affect early site screening involvement. Accordingly, this rule is separable from the amendments to be proposed to Part 51. It is needed now by DOE, and there would be no justification for delay in promulgating it.

e. Party Status for Host State

The point was raised that a host State is entitled to full party status at the outset in NRC licensing proceedings and should have the rights of such a party. An absolute right of participation in NRC licensing proceedings should be declared by 10 CFR Part 60.

Under section 189(a) of the Atomic Energy Act, 42 U.S.C. 2239, a person "whose interest may be affected" is entitled to be admitted to a licensing hearing as a party. Under this statutory provision, there can be no question that the host State has a legal right to be a party. Nevertheless, as in any judicial or administrative proceeding, certain rules of pratice are essential in order for the party's interest in a matter, its contentions with respect thereto, and its claims for relief, to be made a matter of record.

Rights of participation in NRC licensing proceedings are referenced in 10 CFR 60.63. The test of standing are set out in § 2.714. These tests are clearly met for host State participation. The standing tests would be met for affected Indian Tribes as well. [It is also noted that States and arguably affected Indian Tribes can participate under 10 CFR 2.715 without having to take a position on issues by supplementing their intervention petition with contentions as required by § 2.714.) In response to the comments received, the final rule assures that host States and affected Indian Tribes will be permitted to intervene. This has been accomplished by amending 10 CFR 2.714(d). A conforming change is also incorporated in § 60.63(a).

It will not be necessary for such a party to demonstrate its standing, as would otherwise be the case, by a showing of its right under the Atomic Energy Act to be made a party, the nature and extent of its property, financial, or other interest in the proceeding, and the possible effect of any order which may be entered in the proceeding on its interest. Under the amended rule, States and affected

Indian Tribes would have unquestionable legal right to full party status which includes, with respect to all matters affecting its interest, the rights to introduce evidence, put on witnesses, cross-examination, full notice and service of all pleadings, full rights of discovery, and standing to appeal. It should also be noted that non-host States may also participate in licensing proceedings as parties to the extent they meet the customary tests of standing, or as interested States.

Changes to the Proposed Amendments

In addition to changes discussed above, the final rule contains the following substantive changes from the proposed rule as published on January 17, 1985.

Authority Citation

Section 14(a) of Pub. L. 95–601, 42
U.S.C. 2021a would require that DOE notify the Commission as early as possible after commencement of planning for a particular repository. The Commission was directed to notify States in turn. As implied by the preamble to the proposed rule, the Commission considers these requirements to have been superseded by NWPA. The authority citation has been modified accordingly.

Exclusion of Defense Waste Facilities

The Commission's licensing authority extends to two different classes of highlevel waste disposal facilities: repositories used primairily for civilian waste (including spent nuclear fuel) and facilities for defense wastes. Energy Reorganization Act of 1974, sec. 202, 42 U.S.C. 5842. NWPA applies only to some of these facilities-namely, those used at least in part for civilian wastes (i.e., not exclusively for defense wastes). Sec. 8(c), 42 U.S.C. 10107. A commenter suggested that the pre-NWPA procedures should expressly be retained for defense-only facilities, as they were not covered by NWPA and the statute accordingly did not support any change in NRC requirements. The point has merit. However, in accordance with the procedures set out in section 8(b) of NWPA, the President has now determined that the development of repository for the disposal of defense HLW is not required. There is thus no longer any need for regulations dealing specifically with a defense-waste-only repository. To reflect this conclusion, and clarify the scope of the regulations, Section 60.1 is being revised so as to limit the application of the part to facilities "sited, constructed, or operated in accordance with the Nuclear Waste

Policy Act of 1982." Also, the reference in § 60.17(a)(4) to a geologic repository that is not subject to the Waste Policy Act has been deleted.

Definition of "Affected Indian Tribe"

In response to comments, the final rule defines the term "affected Indian Tribe" so as to include, for purposes of these regulations, Indian Tribes having off-reservation rights arising out of "other Federal law" as well as "out of Congressionally ratified treaties", provided that specified findings have been made by the Secretary of the Interior. This would place all Indian Tribes on the same footing as long as their rights arise under Federal law irrespective of the legal form in which such rights may have been documented.

Authority Reference for Site Characterization

One commenter noted that the reference to former 10 CFR § 51.40, in connection with the requirement that DOE is to conduct a program to characterize multiple sites, has been superseded by the NWPA. In response to that comment, § 60.15(c) has been changed to indicate that sec. 113 of the NWPA (42 U.S.C. 10133) is the basis for the site characterization program requirement. The proposed amendments had simply renumbered this section from §§ 60.10 to 60.15 without change.

Authority for Early Site Review by NRC

In response to the comment that the NRC should not rely on the DOE-NRC Procedural Agreement as authority for early site review, the footnote to § 60.18 is revised to delete the reference to the DOE-NRC Procedural Agreement. The Commission relies upon the statutes listed in the authority citation.

Public Comment on NRC Comments to DOE on Site Characterization

On comment stated that issues arising during site characterization could be more readily brought to the Commission's attention by establishing a notice and public comment process for the NRC semi-annual comments to DOE on site characterization. Just as the Commission will solicit comments on its comments on DOE's initial SCP, it wants to allow for public comment on any Commission comments on DOE's semiannual reports. Section 60.18(i) has therefore been changed to include a provision that the Director shall invite public comment on comments which the Director makes to DOE upon review of the DOE semi-annual reports or on any other comments which the Director makes to DOE on site characterization.

Obtaining Host States and Indian Tribe Views on the SCP

Although the Commission continues to find preparation of the draft SCA to be unnecessary, some recognition of its intention to welcome the views of host States and affected Indian Tribes is warranted. Accordingly § 60.18(b) has been changed to provide an opportunity for the host State and affected Indian Tribes for each site to be characterized to present their views on the DOE SCP and their suggestions with respect to NRC comments thereon.

Use of Radioactive Tracers During Site Characterization

One issue raised in the comments related to the scope of the Commission's obligations to concur in the necessity for DOE to use radioactive materials during site characterization. It might be argued that the statutory provision (NWPA § 113(c)(2)(A)) was intended to apply only to the emplacement of discrete packages, for testing purposes, into excavated locations in the respository. However, in view of the unqualified language that "the Secretary may not use any radioactive material at a candidate site unless the Commission concurs that such use is necessary' (emphasis supplied), the regulation has been modified to state expressly that the site characterization plan must also identify any plans DOE may have involving the use of radioactive tracer materials. See § 60.17(a)(2)(ii). Any tracer tests described in the site characterization plans would be subject to the review and concurrence procedure specified in § 60.18(e).

Consultation and Site Review

As stated in the notice of proposed rulemaking, prior provisions pertaining to participation of Indian Tribes have been incorporated in the substantive provisions applicable to States. Further editorial changes (i.e., references to "Tribes") have been made to accomplish this purpose in § 60.62(c).

Separate Views of Commissioner Asselstine

I approve the procedural amendments to 10 CFR 60 in part and disapprove in part. I believe the Commission has gone too far in deleting two very important provisions from the Commission's original procedural rule. These two important elements are: (1) The requirement for NRC review of the Department of Energy's site screening and selection process for a high-level radioactive waste repository; and (2) the requirement for NRC issuance of a draft site characterization analysis of DOE's

site characterization plan for public comment, and staff analysis of those comments.

The Commission issued its licensing procedures for a high-level radioactive waste repository on February 25, 1981. These licensing procedures included NRC review of DOE's site screening and selection process and NRC issuance of a draft site characterization analysis for public comment. These were two provisions which the Commission at the time considered to be important for it to carry out effectively its licensing responsibility of a high-level radioactive waste repository. The Nuclear Waste Policy Act (NWPA) was enacted in 1982. The Congress was aware of NRC's highlevel waste licensing procedures when it passed the NWPA. Congress did not object to these important provisions. However, the Commission is now taking the position that because these provisions are not required by the NWPA, then the Commission should delete them from its regulations. The fact that the new law is silent as to those two provisions does not serve as a justification for deleting these provisions from the Commission's regulations.

I believe the Commission should retain these two very important provisions in 10 CFR Part 60. The Commission's health and safety and environmental protection responsibilities warrant NRC review of DOE's site screening and selection process. I also believe that NRC issuance of its site characterization analysis for public comment will contribute to a more rigorous and thorough review of the DOE site characterization plans, which in turn, will enhance public confidence. What the Commission considered important to carry out its health and safety responsibilities in 1981 is still important and has not been changed by the NWPA.

Environmental Impact

Pursuant to section 121(c) of the Nuclear Waste Policy Act, this rule does not require the preparation of an environmental impact statement under section 102(2)(C) of the National Environmental Policy Act of 1969 or any environmental review under subparagraph (E) or (F) of section 102(2) of such act.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1989 [44 U.S.C. 3501 et seq.). These requirements were approved by the

Office of Management and Budget-Approval No. 3150-0127.

Regulatory Flexibility Act Certification

In accordance with the Regulatory
Flexibility Act of 1980 (5 U.S.C. 605(b)),
the Commission certifies that this rule
will not have a significant economic
impact on a substantial number of small
entities. This rule relates to the licensing
of only one entity, the U.S. Department
of Energy, which does not fall within the
scope of the definition of "small
entities" set forth in the Regulatory
Flexibility Act.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection. Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 60

High-level waste, Nuclear power plants and reactors, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Waste treatment and disposal.

Issuance

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, the Nuclear Waste Policy Act of 1982, and 5 U.S.C. 553, the Nuclear Regulatory Commission is adopting the following amendments to 10 CFR Part 2 and 10 CFR Part 60.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority citation for Part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended. Pub. L. 87–615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 938, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200-2.206 also issued under secs. 186, 234, 68 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Sections 2.600-2.606 also

issued under sec. 102. Pub. L. 91–190, 83 Stat. 853 as amended (42 U.S.C. 4332) Section 2.700a, also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770, 2.780 also issued under 5 U.S.C. 557. Section 2.790 also issued under 5 U.S.C. 557. Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.608 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85–256, 71 Stat. 579 as amended (42 U.S.C. 2039). Subpart K also issued under Sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Appendix A also issued under sec. 6, Pub. L. 91–580, 84 Stat. 1437 (42 U.S.C. 2135).

Section 2.714(d) is revised to read as follows:

§ 2.714 Intervention.

(d) The Commission, the presiding officer, or the atomic safety and licensing board designated to rule on petitons to intervene and/or requests for hearing shall permit intervention, in any hearing on an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area, by the State in which such area is located and by any affected Indian Tribe as defined in Part 60 of this chapter. In all other circumstances, such ruling body or officer shall, in ruling on a petition for leave to intervene, consider the following factors, among other things:

- (1) The nature of the petitioner's right under the Act to be made a party to the proceeding.
- (2) The nature and extent of the petitioner's property, financial, or other interest in the proceeding.
- (3) The possible effect of any order which may be entered in the proceeding on the petitioner's interest.

PART 60—DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES

The authority citation for Part 60 is revised to read as follows:

Authority: Secs. 51, 53, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 929, 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2071, 2073, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95–601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); sec. 121, Pub. L. 97–425, 96 Stat. 2228 (42 U.S.C. 10141).

For the purposes of Sec. 223, 68 Stat. 958, as amended [42 U.S.C. 2273], §§ 60.71 to 60.75 are issued under Sec. 1610, 68 Stat. 950, as amended [42 U.S.C. 2201(0)].

4. Section 60.1 is revised to read as follows:

§ 60.1 Purpose and scope.

This part prescribes rules governing the licensing of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated in accordance with the Nuclear Waste Policy Act of 1982. This part does not apply to any activity licensed under another part of this chapter.

5. Section 60.2 is amended by removing the definitions of "Indian Tribe" and "Tribal Organization" and inserting, in the appropriate alphabetical location, a definition of the term "affected Indian Tribe" to read as follows:

§ 60.2 Definitions.

"Affected Indian Tribe" means any Indian Tribe (1) within whose reservation boundaries a repository for high-level radioactive waste or spent fuel is proposed to be located; or (2) whose Federally defined possessory or usage rights to other lands outside of the reservation's boundaries arising out of Congressionally ratified treaties or other Federal law may be substantially and adversely affected by the locating of such a facility; Provided, That the Secretary of the Interior finds, upon the petition of the appropriate governmental officials of the Tribe, that such effects are both substantial and adverse to the Tribe.

§ 60.10 [Redesignated as § 60.15]

6. Section 60.10 is redesignated as § 60.15. In new § 60.15, paragraph (c) is revised to read as follows:

§ 60.15 Site characterization.

(c) As provided by Sec. 113 of the Nuclear Waste Policy Act (42 U.S.C. 10133), DOE is also required to conduct a program of site characterization, including in situ testing at depth, with respect to alternate sites.

§ 60.11 [Removed]

- 7. Section 60.11 is removed.
- 8. Sections 60.16 through 60.18 are added to read as follows:

§ 60.16 Site characterization plan required.

Before proceeding to sink shafts at any area which has been approved by the President for site characterization, DOE shall submit to the Director, for review and comment, a site characterization plan for such area. DOE shall defer the sinking of such shafts until such time as there has been an opportunity for Commission comments thereon to have been solicited and considered by DOE.

§ 60.17 Contents of site characterization plan.

The site characterization plan shall contain—

- (a) A general plan for site characterization activities to be conducted at the area to be characterized, which general plan shall include:
- (1) A description of such area, including information on quality assurance programs that have been applied to the collection, recording, and retention of information used in preparing such description.

(2) A description of such site characterization activities, including the following.

following—

(i) The extent of planned excavations;

- (ii) Plans for any onsite testing with radioactive material, including radioactive tracers, or nonradioactive material;
- (iii) Plans for any investigation activities that may affect the capability of such area to isolate high-level radioactive waste;
- (iv) Plans to control any adverse impacts from such site characterization activities that are important to safety or that are important to waste isolation; and
- (v) Plans to apply quality assurance to data collection, recording, and retention.
- (3) Plans for the decontamination and decommissioning of such area, and for the mitigation of any significant adverse environmental impacts caused by site characterization activities, if such area is determined unsuitable for application for a construction authorization for a geologic repository operations area;

(4) Criteria, developed pursuant to section 112(a) of the Nuclear Waste Policy Act of 1982, to be used to determine the suitability of such area for the location of a geologic repository; and

(5) Any other information which the Commission, by rule or order, requires.

(b) A description of the possible waste form or waste package for the high-level radioactive waste to be emplaced in such geologic repository, a description (to the extent practicable) of the relationship between such waste form or waste package and the host rock at such area, and a description of the activities being conducted by DOE with respect to such possible waste form or waste package or their relationship; and

(c) A conceptual design for the geologic repository operations area that takes into account likely site-specific requirements.

§ 60.18 Review of site characterization activities.2

(a) The Director shall cause to be published in the Federal Register a notice that a site characterization plan has been received from DOE and that a staff review of such plan has begun. The notice shall identify the area to be characterized and the NRC staff members to be consulted for further information.

(b) The Director shall make a copy of the site characterization plan available at the Public Document Room. The Director shall also transmit copies of the published notice of receipt to the Governor and legislature of the State in which the area to be characterized is located and to the governing body of any affected Indian Tribe. The Director shall provide an opportunity, with respect to any area to be characterized, for the State in which such area is located and for affected Indian Tribes to present their views on the site characterization plan and their suggestions with respect to comments thereon which may be made by NRC. In addition, the Director shall make NRC staff available to consult with States and affected Indian Tribes as provided in Subpart C of this part.

(c) The Director shall review the site characterization plan and prepare a site characterization analysis with respect to such plan. In the preparation of such site characterization analysis, the Director may invite and consider the views of interested persons on DOE's site characterization plan and may review and consider comments made in connection with public hearings held by

DOE.

(d) The Director shall provide to DOE the site characterization analysis together with such additional comments as may be warranted. These comments shall include either a statement that the Director has no objection to the DOE's site characterization program, if such a statement is appropriate, or specific objections with respect to DOE's program for characterization of the area concerned. In addition, the Director may make specific recommendations

pertinent to DOE's site characterization

(e) If DOE's planned site characterization activities include onsite testing with radioactive material, including radioactive tracers, the Director's comments shall include a determination regarding whether or not the Commission concurs that the proposed use of such radioactive material is necessary to provide data for the preparation of the environmental reports required by law and for an application to be submitted under § 60.22 of this part.

(f) The Director shall publish in the Federal Register a notice of availability of the site characterization analysis and a request for public comment. A reasonable period, not less than 90 days, shall be allowed for comment. Copies of the site characterization analysis and of the comments received shall be made available at the Public Document Room.

(g) During the conduct of site characterization activities, DOE shall report not less than once every six months to the Commission on the nature and extent of such activities and the information that has been developed, and on the progress of waste form and waste package research and development. The semiannual reports shall include the results of site characterization studies, the identification of new issues, plans for additional studies to resolve new issues, elimination of planned studies no longer necessary, identification of decision points reached and modifications to schedules where appropriate. DOE shall also report its progress in developing the design of a geologic repository operations area appropriate for the area being characterized, noting when key design parameters or features which depend upon the results of site characterization will be established. Other topics related to site characterization shall also be covered if requested by the Director.

(h) During the conduct of site characterization activities, NRC staff shall be permitted to visit and inspect the locations at which such activities are carried out and to observe excavations, borings, and in situ tests as they are done.

(i) The Director may comment at any time in writing to DOE, expressing current views on any aspect of site characterization. In particular, such comments shall be made whenever the Director, upon review of comments invited on the site characterization analysis or upon review of DOE's semiannual reports, determines that there are substantial new grounds for

^{*}In addition to the review of site characterization activities specified in this section, the Commission contemplates an ongoing review of other information on site investigation and site characterization, in order to allow early identification of potential licensing issues for timely resolution. This activity will include, for example, a review of the environmental assessments prepared by DOE at the time of site nomination, and review of issues related to long lead time exploratory shaft planning and procurement actions by DOE prior to issuance of site characterization plans.

making recommendations or stating objections to DOE's site characterization program. The Director shall invite public comment on any comments which the Director makes to DOE upon review of the DOE semiannual reports or on any other comments which the Director makes to DOE on site characterization.

(j) The Director shall transmit copies of the site characterization analysis and all comments to DOE made by the Director under this section to the Governor and legislature of the State in which the area to be characterized is located and to the governing body of any affected Indian Tribe. When transmitting the site characterization analysis under this paragraph, the Director shall invite the addressees to review and comment thereon.

(k) All correspondence between DOE and the NRC under this section, including the reports described in paragraph (g), shall be placed in the

Public Document Room.

(l) The activities described in paragraphs (a) through (k) of this section constitute informal conference between a prospective applicant and the staff, as described in § 2.101(a)(1) of this chapter, and are not part of a proceeding under the Atomic Energy Act of 1954, as amended. Accordingly, neither the issuance of a site characterization analysis nor any other comments of the Director made under this section constitutes a commitment to issue any authorization or license or in any way affect the authority of the Commission, the Atomic Safety and Licensing Appeal Board, Atomic Safety and Licensing Boards, other presiding officers, or the Director, in any such proceeding.

9. Subpart C is revised to read as

follows:

Subpart C-Participation by State Governments and Affected Indian Tribes

Sec

60.61 Provision of information.

60.62 Site review.

60.63 Participation in license reviews.

60.64 Notice to States.

60.65 Representation.

Subpart C—Participation by State Governments and Affected Indian Tribes

§ 60.61 Provision of information.

(a) The Director shall provide to the Governor and legislature of any State in which a geologic repository operations area is or may be located, and to the governing body of any affected Indian Tribe, timely and complete information regarding determinations or plans made by the Commission with respect to the

site characterization, siting, development, design, licensing, construction, operation, regulation, permanent closure, or decontamination and dismantlement of surface facilities, of such geologic repository operations area.

(b) For purposes of this section, a geologic repository operations area shall be considered to be one which "may be located" in a State if the location thereof in such State has been described in a site characterization plan submitted to the Commission under this part.

(c) Notwithstanding paragraph (a) of this section, the Director is not required to distribute any document to any entity if, with respect to such document, that entity or its counsel is included on a service list prepared pursuant to Part 2 of this chapter.

(d) Copies of all communications by

the Director under this section shall be placed in the Public Document Room, and copies thereof shall be furnished to

§ 60.62 Site review.

(a) Whenever an area has been approved by the President for site characterization, and upon request of a State or an affected Indian Tribe, the Director shall make NRC staff available to consult with representatives of such States and Tribes.

(b) Requests for consultation shall be made in writing to the Director.

(c) Consultation under this section may include:

(1) Keeping the parties informed of the Director's views on the progress of site characterization.

(2) Review of applicable NRC regulations, licensing procedures, schedules, and opportunities for State and Tribe participation in the Commission's regulatory activities.

(3) Cooperation in development of proposals for State and Tribe participation in license reviews.

§ 60.63 Participation in license reviews.

(a) State and local governments and affected Indian Tribes may participate in license reviews as provided in Subpart G of Part 2 of this chapter. A State in which a repository for high-level radioactive waste is proposed to be located and any affected Indian Tribe shall have an unquestionable legal right to participate as a party in such proceedings.

(b) In addition, whenever an area has been approved by the President for site characterization, a State or an affected Indian Tribe may submit to the Director a proposal to facilitate its participation in the review of a site characterization plan and/or license application. The proposal may be submitted at any time and shall contain a description and schedule of how the State or affected Indian Tribe wishes to participate in the review, or what services or activities the State or affected Indian Tribe wishes NRC to carry out, and how the services or activities proposed to be carried out by NRC would contribute to such participation. The proposal may include educational or information services (seminars, public meetings) or other actions on the part of NRC, such as establishing additional public document rooms or employment or exchange of State personnel under the Intergovernmental Personnel Act.

(c) The Director shall arrange for a meeting between the representatives of the State or affected Indian Tribe and the NRC staff to discuss any proposal submitted under paragraph (b) of this section, with a view to identifying any modifications that may contribute to the effective participation by such State or

Tribe.

(d) Subject to the availability of funds, the Director shall approve all or any part of a proposal, as it may be modified through the meeting described above, if it is determined that:

(1) The proposed activities are suitable in light of the type and magnitude of impacts which the State or affected Indian Tribe may bear;

(2) The proposed activities:

(i) Will enhance communications between NRC and the State or affected Indian Tribe;

(ii) Will make a productive and timely contribution to the review; and

(iii) Are authorized by law.

(e) The Director will advise the State or affected Indian Tribe whether its proposal has been accepted or denied, and if all or any part of proposal is denied, the Director shall state the reason for the denial.

(f) Proposals submitted under this section, and responses thereto, shall be made available at the Public Document Room.

§ 60.64 Notice to States.

If the Governor and legislature of a State have jointly designated on their behalf a single person or entity to receive notice and information from the Commission under this part, the Commission will provide such notice and information to the jointly designated person or entity instead of the Governor and legislature separately.

§ 60.65 Representation.

Any person who acts under this subpart as a representative for a State (or for the Governor or legislature thereof) or for an affected Indian Tribe shall include in the request or other submission, or at the request of the Commission, a statement of the basis of his or her authority to act in such representative capacity.

Dated at Washington, DC, this 22d day of July 1986.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.
[FR Doc. 88–16898 Filed 7–29–86; 8:45 am]

FEDERAL HOME LOAN BANK BOARD

12 CFR Parts 500, 501, and 522 [No. 86-755]

Organization and Operation

Dated: July 24, 1986.

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rule.

SUMMARY: By these amendments the Federal Home Loan Bank Board ("Board") establishes a new Office of Regulatory Policy, Oversight, and Supervision ("ORPOS") as part of the Federal Home Loan Bank System. This organizational restructuring is a follow-up to the Board's delegation of field examination functions to its Principal Supervisory Agents. It will enable the Board to exercise more efficient oversight and control of the examination/supervision functions as performed by the Principal Supervisory Agents and their staffs at the Federal Home Loan Banks ("Banks").

EFFECTIVE DATE: September 27, 1986.

FOR FURTHER INFORMATION CONTACT: Randy W. Thomas, Attorney, Administration Division, Office of General Counsel, (202) 377–6550, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: By its Resolution No. 85-186 of March 14, 1985, the Board delegated to its Principal Supervisory Agent at each Federal Home Loan Bank the functions of examining institutions subject to the Board's jurisdiction. The Board noted that it had previously delegated its supervisory functions to the Banks and found on the basis of recommendations of a Task Force composed of both Bank and Board staff that it was desirable for field examination functions also to be performed by Bank personnel assigned to and under the direction of the Principal Supervisory Agents. The Board noted that such delegation of function

was within its authority to delegate performance of any function of the Board except with regard to promulgation of rules and regulations and for certain adjudications.

Upon consideration of recommendation of the staff and a second Task Force charged with making recommendations for strengthening the Office of Examinations and Supervision following the field reorganization, the Board has determined that its purpose of improving the effectiveness of its examination and supervisory functions would be served by establishing within the Bank System a new Office of Regulatory Policy, Oversight, and Supervision through which to exercise its statutory responsibility to oversee, control, and, where necessary, improve those functions. Basic to this determination was the Board's finding that such restructuring would give it the managerial flexibility it urgently needs to respond more successfully to the complex challenges posed by present thrift industry conditions. To take advantage of the economies and efficiencies of combined operations, it is the Board's intention that the new Office of Regulatory Policy, Oversight, and Supervision will share, to the extent practicable, accounting, budgeting, payroll, personnel, and other administrative services with the Office of Finance.

Pursuant to 12 CFR 508.11 and 508.14, the Board finds that, because these amendments relate to urgently needed flexibility in Board organization, management, and personnel, notice and public procedure are unnecessary, as is the 30-day delay of the effective date.

List of Subjects in 12 CFR Parts 500, 501, and 522

Organization and channelling of functions, Claims, Conflict of interest, Federal home loan banks.

Accordingly, the Board hereby amends Parts 500 and 501, Subchapter A, and Part 522, Subchapter B, Chapter V, Title 12, Code of Federal Regulations, as set forth below:

SUBCHAPTER A-GENERAL

PART 500—ORGANIZATION AND CHANNELLING OF FUNCTIONS

 The authority citation for Part 500 is revised to read as follows:

Authority: Sec. 17, 47 Stat. 736, as amended (12 U.S.C. 1437); sec. 402, 48 Stat. 1256, as amended (12 U.S.C. 1725); Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943–48 Comp., p. 1071; Reorg. Plan No. 6 of 1961, reprinted in 12 U.S.C.A. 1437 App. (West Supp. 1986).

§ 500.18 [Removed]

2. Remove § 500.18.

§ 500.40 [Amended]

Amend § 500.40 by removing the authority citation located at the end of the section.

PART 501-OPERATIONS

4. The authority citation for Part 501 is revised to read as follows:

Authority: Sec. 17, 47 Stat. 736, as amended, (12 U.S.C. 1437); secs. 402, 403, 48 Stat. 1256, 1257, as amended (12 U.S.C. 1725, 1726); Reorg, Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943–48 Comp., p. 1071; Reorg, Plan No. 6 of 1961, reprinted in 12 U.S.C.A. 1437 App. (West Supp. 1986).

§501.11 [Amended]

5. Amend § 501.11 by inserting immediately after the word "supervising" in the second sentence the words "and examining".

SUBCHAPTER B-FEDERAL HOME LOAN BANK SYSTEM

PART 522—ORGANIZATION OF THE BANKS

The authority citation for Part 522 is revised to read as follows:

Authority: Sec. 5 B, 47 Stat. 727, as added by sec. 4, 80 Stat. 824, as amended (12 U.S.C. 1425b); secs. 6-7, 47 Stat. 727, 730, as amended (12 U.S.C. 1426-1427); sec. 17, 47 Stat. 736, as amended (12 U.S.C. 1437); sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464); secs. 402-403, 407, 48 Stat. 1256-1257, 1260, as amended (12 U.S.C. 1725-1726, 1730); sec. 207, 62 Stat. 692, as added by sec. 1a, 76 Stat. 1123, as amended (16 U.S.C. 207); sec. 602, 92 Stat. 2115, as amended (42 U.S.C. 8101 et seq.); Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943-48 Comp., p. 1071; Reorg. Plan No. 6 of 1961, reprinted in U.S.C.A. 1437 App. (West Supp. 1986).

7. Add a new § 522.90 to read as follows:

§ 522.90 Office of Regulatory Policy, Oversight, and Supervision.

(a) General. (1) An Office of Regulatory Policy, Oversight, and Supervision ("ORPOS") is hereby established, which shall be located in the Washington, DC, metropolitan area, and shall perform the functions set forth in paragraph (b) of this section.

(2) ORPOS shall be headed by a Director, who shall have responsibility for the performance of its functions. The Board shall appoint and fix the compensation of the Director. The Director may, with the consent of the Board, select one or more Deputy Directors, Associate Directors, or Assistant Directors. As authorized in writing by the Director, the Deputy,

Associate, and Assistant Directors may exercise the functions of the Director.

(b) Functions of the Office of Regulatory Policy, Oversight, and Supervision. (1) ORPOS shall advise and assist the Principal Supervisory Agents and the Board with respect to the activities of officers or employees of the Banks as agents of the Board and the Federal Savings and Loan Insurance Corporation. ORPOS shall assist in the processes of examination and supervision and advise as to any necessary or appropriate improvement or standardization of such processes. ORPOS shall advise and assist the Principal Supervisory Agents and Board with respect to matters of policy, legislation, or regulation relating to functions as the Board may request. ORPOS shall perform directly for the Board any monitoring, evaluation, postaudit review, processing of applications, or other functions deemed necessary or appropriate by the Board to ensure the integrity and efficiency of the examination and supervisory activities. In addition, ORPOS shall succeed to any delegation of authority by the Board to the former Office of Examinations and Supervision, or its Director, or employees, and ORPOS shall perform any duties arising from such delegation and succession.

(2) ORPOS shall maintain an account in a depository approved by the Board. Such account shall be subject to withdrawal by check or draft signed by either the Director or by another person designated by the Board. Each Bank shall from time to time promptly forward to ORPOS, upon receipt of a statement, the amount of its share of the expenditures made by ORPOS during a designated period. All of the foregoing receipts from the Banks shall be deposited in the account referred to in this section and disbursed as provided in paragraph (c) of this section.

(c) Budget and Expenses. ORPOS shall annually submit to the Board by December 1 a budget of its proposed expenditures for the following calendar year. After such budget has been approved by the Board, the Director may make disbursements thereunder from the funds provided for in paragraph (b)(2) of this section. Following approval by the Board, the Director shall transmit a copy of the budget to each of the Principal Supervisory Agents. The Director may, without further authority, make a transfer from any excess allotment in the budget to any insufficient allotment. However, transfers to allotments for compensation or rent of office quarters, as well as any proposed changes that would increase

the total of the approved budget, shall be submitted for approval in the same manner as the original budget was submitted. In addition, the Director shall, as directed by the Board, make disbursements from the funds provided for in paragraph (b)(2) of this section in payment of such expenses and costs not covered by the approved budget and which are deemed appropriate.

8. Amend Part 522 by removing the authority citations located at the ends of the applicable sections of this Part.

By the Federal Home Loan Bank Board. John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 86-17085 Filed 7-29-86; 8:45 am]

SMALL BUSINESS ADMINISTRATION 13 CFR Part 115

Surety Bond Guarantee

AGENCY: Small Business Administration.
ACTION: Final rule.

SUMMARY: This rule revises 13 CFR Part 115 to make it consistent with § 18014 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99–272, approved April 7, 1986), which increased the amount of the contracts which SBA is permitted to guarantee from \$1,000,000 to \$1,250,000. Since this rule merely implements the cited statute, it is published in final form, without opportunity for comment.

DATES: This rule is effective July 30,

ADDRESS: Howard F. Huegel, Director, Office of Surety Guarantees, Small Business Administration, 4040 No. Fairfax Drive, Arlington, VA. 22203, (703) 235–2900.

FOR FURTHER INFORMATION CONTACT: Howard F. Huegel (703) 235–2900.

SUPPLEMENTARY INFORMATION: This rule is not a major rule under the requirements of E.O. 12291. It will not result in an annual economic effect of \$100,000,000 or more because it merely increases the size of the contract which may now be guaranteed. Nor will the rule result in a major increase in costs for consumers, individual industries, Federal, state or local government agencies or geographic regions. There will be no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based businesses to compete with foreign based businesses in domestic or export markets.

SBA certifies, pursuant to the Regulatory Flexibility Act, (5 U.S.C. 601 et seq.), that this final rule will not have a significant economic impact on a substantial number of small entities since only a small percentage of the contracts which are currently turned down for surety bond guarantees are turned down solely because the size of the contract exceeds \$1,000,000. There are no alternatives to this rule since the change is mandated by statute. These rules do not duplicate, overlap or conflict with any existing Federal rules.

Pursuant to the Administrative Procedure Act (5 U.S.C. 553(b)) the SBA finds that notice and public comment procedures are unnecessary because this change in the current regulations has been mandated by statute.

This final rule does not contain any requirements which are subject to approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. ch. 35).

List of Subjects in 13 CFR Part 115

Surety Bond Guarantee.

1. The Authority citation for Part 115 remains unchanged and continues to read as follows:

Authority: Title IV—Part B, of the Small Business Investment Act of 1958 (15 U.S.C. 694a, 694b), and the Inspector General Act of 1978 (5 U.S.C., App. 1)

2. Accordingly, pursuant to the authority contained in section 5(b)(6) of the Small Business Act (15 U.S.C. 634(b)(6)) and section 308(c) of the Small Business Investment Act (15 U.S.C. 687(c)), Part 115, Title 13 of the Code of Federal Regulations is revised as follows:

PART 115-SURETY BOND GUARANTEE

The last sentence of § 115.2(a) Policy is revised to read as follows:

§ 115.2 Policy.

(a) * * *

On multiple requests for bond guarantees by one contractor on one project, the aggregate amount of the contracts shall not exceed \$1,250,000.

The first sentence of § 115.8(a)(3) is revised to read as follows:

§ 115.8 SBA's underwriting review.

(a) * * *

(3) The bond is either a bid, performance, or payment bond issued in connection with a contract not exceeding \$1,250,000 in face value and is the type of bond listed in the "Contract Bonds" section of the Rating Manual of the Surety Association of America. * * *

Section 115.10(d)(1) is revised to read as follows:

§ 115.10 Surety bonding line.

* * * *

(d) * * *

(1) Contracts exceeding \$1,250,000 in face value are not eligible.

Section 115.11(a)(1) is revised to read as follows:

§ 115.11 Loss under bond.

(a) * * *

(1) The total contract amount at the time of execution of the bond or bonds exceeds \$1,250,000 in face value, or

(Catalog of Federal Domestic Assistance No. 59.016, Bond Guaranty for Surety Companies)

Dated: July 23, 1986.

Charles L. Heatherly,

Acting Administrator.

[FR Doc. 86–17090 Filed 7–29–86; 8:45 am]

13 CFR Part 115

Surety Bond Guarantee

AGENCY: Small Business Administration.
ACTION: Final rule correction.

SUMMARY: This document corrects an SBA Emergency Final Regulation which made certain changes in the Surety Bond Guarantee Program with respect to the lowering of the guarantee to 80 percent for bonds on a contract up to \$250,000 and the raising of the premium and of the guarantee fee which may be charged by the Surety and by SBA. That regulation, which was published in the Federal Register on June 9, 1986 (51 FR 20922), and the Supplementary Information preceding it, mistakenly read that SBA would guarantee up to 80 percent of a contract up to \$1,000,000 in face value. It should have read that SBA would guarantee up to 80 percent of a contract up to \$1,250,000. The increase in the size of the contract which SBA may now guarantee is due to a statutory change. (See Pub. L. 99-272 Consolidated Omnibus Budget Reconciliation Act of 1985, section 18014, approved April 7, 1986.)

FOR FURTHER INFORMATION CONTACT: Howard F. Huegel, Director, Office of Surety Guarantees, Small Business Administration, 4040 No. Fairfax Drive, Arlington, Va. 22203, (703) 235–2900.

The following correction is made in FR Doc. 86–12548 appearing on 20922–20923 in the issue of June 9, 1986.

On page 20923 § 115.2 Policy is corrected by revising it to read as follows:

§ 115.2 Policy.

(b) Percentage guarantee. SBA may guarantee up to eighty percent (80%) of the loss incurred and paid under a bond on a contract up to \$1,250,000 in face value.

(Catalog of Federal Domestic Assistance No. 59.016, Bond Guaranty for Surety Companies)
Dated: July 23, 1986.

4

Charles L. Heatherly,

Acting Administrator.

[FR Doc. 86-17091 Filed 7-29-86; 8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 86-AWA-6]

Alteration of VOR Federal Airways—

AGENCY: Federal Aviation Administration (FAA), DOT. ACTION: Final rule; change of effective

SUMMARY: On July 9, 1986, the FAA published a final rule altering Federal Airways V-194, V-198, V-477 and V-556 with an effective date of August 28, 1986. It is necessary to delay the effective date for implementation. This action changes the effective date of the final rule to February 12, 1987.

EFFECTIVE DATE: 0901 GMT, February 12,

FOR FURTHER INFORMATION CONTACT: Mr. Brent A. Fernald, Airspace and Air Traffic Rules Branch (ATO-230), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9255.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 86–15358, published on July 9, 1986, (51 FR 24813) cited as the effective date for implementation August 28, 1986. Because of slippage in the commissioning of the new runways at Houston Intercontinental and technical problems, it is necessary to delay and change the effective date of the final rule. This action postpones the effective date of the final rule to February 12, 1987.

The FAA has determined that this regulation only involves an established

body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore-(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, VOR Federal Airways.

Adoption of the Correction

PART 71-[AMENDED]

Accordingly, pursuant to the authority delegated to me, Federal Register Document 86–15358, as published in the Federal Register on July 9, 1986, (51 FR 24813) is amended by changing the effective date from "August 28, 1986" to "February 12, 1987."

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); 14 CFR 11.69

Issued in Washington, DC, on July 23, 1986. Daniel J. Peterson,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 86-17018 Filed 7-29-86; 8:45 am] BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 86-ASO-9]

Designation of Transition Area, Foley, AL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Correction to final rule.

SUMMARY: This action corrects Federal Register Document 86–13332 published in the Federal Register on June 13, 1986, which designated the Foley, Alabama, transition area.

EFFECTIVE DATE: 0901 UTC, August 28, 1986.

FOR FURTHER INFORMATION CONTACT:

Donald Ross, Supervisor, Air space Section, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: [404] 763-7646.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 86-13332 published on June 13, 1986, designated the Foley, Alabama, transition area. Subsequent to publication of the Final Rule, it was discovered that the description of the new transition area erroneously referred to exclusion of the Fairhope, Alabama, transition area. The exclusion should have referred to the Mobile, Alabama, transition area. This correction to the Final Rule will incorporate the proper exclusion. To avoid confusion the complete transition area description, as corrected, is presented in the text of this document. Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in FAA Order 7400.6B, dated January 2, 1986.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations designates the Foley, Alabama, transition area to accommodate Instrument Flight Rule operations at Foley Municipal Airport.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since the is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Transition area.

Adoption of the Amendment

PART 71-[AMENDED]

Accordingly, pursuant to the authority delegated to me, Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, as follows:

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); 14 CFR 11.69.

2. By amending § 71.181 as follows:

Foley, AL-[New]

That airspace extending upward from 700 feet above the surface within a 6.5 -mile radius of Foley Municipal Airport (Lat. 30°25'45"N., Long. 87°42'03' W), excluding that portion which coincides with the Mobile and Gulf Shores, AL, transiton areas.

Issued in East Point, Georgia, on July 21, 1986.

James L. Wright,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 86–17017 Filed 7–29–86; 8:45 am]

14 CFR Part 71

[Airspace Docket No. 86-AWP-24]

Amended Control Zone Hours, Yuba County Airport, California

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This action will change the Yuba County Airport control zone from a full time to a part time control zone. The Marysville Flight Service Station is in operation from 0600 to 2100 hours local time, daily and is responsible for providing weather reporting service at the Yuba County Airport. One of the requirements to have a control zone is that hourly and special weather observations must be taken at the airport upon which the control zone is designated. This action will change the control zone hours to match the hours that weather reporting services are available at the Yuba County Airport. DATES: Effective date-0901 UTC.

October 23, 1986.

Comments must be received on or before September 8, 1986.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, Airspace Branch, AWP-520, Docket No. 86-AWP-24, Air Traffic Divison, P.O. Box 90027, WWPC, Los Angeles, California 90009.

The official docket may be examined in the Office of the Regional Counsel, Western-Pacific Region, Federal Aviation Administration, Room 6W14, at 15000 Aviation Boulevard, Lawndale, California.

An informal docket may also be examined during normal business hours at the Office of the Manager, Airspace Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: Frank T. Torikai, Airspace Specialist, Airspace Branch, AWP-520, Air Traffic

Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90260, telephone (213) 297– 1649.

SUPPLEMENTARY INFORMATION:

Request For Comments on The Rule

Although this action is in the form of a final rule which involves amending the description of the Yuba County Airport, California, control zone and was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the rule that might suggest the need to modify the rule.

The Rule

The purpose of this amendment to § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is to change the Yuba County Airport control zone from a full time to a part time control zone. Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6B, dated January 2, 1986.

Under the circumstances presented, the FAA concludes that there is an immediate need for a regulation to amend the description of the Yuba County Airport control zone. Therefore, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest. For the same reasons, I find that good cause exists for making this amendment effective coincident with the next charting date.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a

routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Control zones.

Adoption of the Amendment

PART 71-[Amended]

Accordingly, pursuant to the authority delegated to me, Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended as follows:

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); 14 CFR 11.69.

2. Section 71.171 is amended as follows:

Marysville Yuba County Airport, CA— [Amended]

Add the following sentence to the end of the present control zone description: "This control zone is effective from 0600 to 2100 hours local time, daily or during specific dates and times established in advance by a Notice to Airmen which thereafter will be continuously published in the Airport/Facility Directory.

Issued in Los Angeles, California, on July 22, 1986.

Wayne C. Newcomb,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 86-17016 Filed 7-29-86; 8:45 am] BILLING CODE 4910-13-M

INTERNATIONAL TRADE COMMISSION

19 CFR Part 213

Trade Remedy Assistance

AGENCY: International Trade Commission.

ACTION: Fifial rules; correction.

SUMMARY: Through an administrative error, the effective date was deleted from a U.S. International Trade Commission document containing the Final Commission Rules pertaining to Trade Remedy Assistance. This notice corrects that deletion.

FOR FURTHER INFORMATION CONTACT: Jeffrey L. Gertler, Esq., Trade Remedy Assistance Center, U.S. International Trade Commission, Room 130, 701 E Street NW., Washington, DC 20436, telephone (202) 523–0488. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 724–0002.

In FR Doc. 86–16023, published in the Federal Register of Friday, July 18, 1986 on page 25999, the preamble is corrected by adding an effective date for the document to read as follows:

"Effective Date: July 18, 1986."

By order of the Commission. Issued: July 22, 1986.

Kenneth Mason.

Secretary.

[FR Doc. 17095 Filed 7-29-86; 6:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 182 and 184

[Docket No. 81N-0368]

Hydrogen Peroxide; Affirmation of GRAS Status With Specific Limitations

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug
Administration (FDA) is affirming that
hydrogen peroxide is generally
recognized as safe (GRAS) with specific
limitations as a direct human food
ingredient. The safety of this ingredient
has been evaluated under the
comprehensive safety review conducted
by the agency.

EFFECTIVE DATE: August 29, 1986.

5690.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-

SUPPLEMENTARY INFORMATION: In the Federal Register of November 17, 1983 (48 FR 52323), FDA published a proposal to affirm that hydrogen peroxide is GRAS, with specific limitations, for use as a direct human food ingredient. FDA published this proposal in accordance with its announced review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the report of the Select Committee on GRAS Substances (the Select Committee) on hydrogen peroxide have been made available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers

Lane, Rockville, MD 20857. Copies of these documents are available for public purchase from the National Technical Information Service (NTIS), as announced in the proposal.

In addition to proposing to affirm the GRAS status of hydrogen peroxide with specific limitations, FDA gave public notice that it was unaware of any priorsanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture (USDA) or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have the prior-sanctioned uses of this ingredient recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181), or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

One comment expressed a belief that a prior sanction exists for the use of hydrogen peroxide as an antimicrobial agent. The comment, however, did not present any proof of such a prior sanction. The comment did provide a copy of a 1940 patent for the use of hydrogen peroxide to produce thermophile-free starch. The agency finds that this patent is not evidence of a prior sanction. However, the agency has considered the claim that hydrogen peroxide is GRAS for use as an antimicrobial agent to produce thermophile-free starch as a comment on the proposal and is including this use in this GRAS regulation.

No other reports of prior sanctions were received. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of this ingredient under conditions different from those set forth in this final rule has been waived.

In response to the publication of the proposed regulation on hydrogen peroxide, FDA received two requests for an extension of the comment period. In a notice published in the Federal Register of January 27, 1984 (49 FR 3490), the agency granted a 90-day extension.

I. Uses of Hydrogen Peroxide Reported in Comments

FDA received seven comments on the proposed rule during the comment period. None of these comments

questioned the agency's tentative determination that the use of hydrogen peroxide is GRAS. Therefore, FDA is affirming as GRAS the uses of the substance that were listed in the proposal.

Each of the comments, however, requested that FDA revise the proposed regulation to affirm as GRAS certain current industry uses of hydrogen peroxide as a processing aid. The following is a summary of the additional uses of hydrogen peroxide that were reported to the agency in these seven comments:

- 1. One comment from the representative of a manufacturer of food emulsifiers that contain fatty acid esters requested that the agency amend the final rule to permit the use of hydrogen peroxide as a bleaching agent in these emulsifiers. The comment described the process for bleaching food emulsifiers that contain fatty acid esters used by this manufacturer and presumably by others. The comment described this bleaching process as including the addition of a 50-percent aqueous solution of hydrogen peroxide to these emulsifiers at levels that do not exceed 2.5 percent (1.25 percent hydrogen peroxide on a 100-percent active basis). The comment reported that residual hydrogen peroxide is removed from the emulsifiers by heating the bleached product under reduced pressure. The comment reported that residual peroxide has not been detected in the bleached product when analyzed using standard peroxide analytical methods.
- 2. A comment from a national trade association reported the use of hydrogen peroxide as an antimicrobial and a bleaching agent in the production of starch and food starch modified and as an agent to remove residual sulfur dioxide in the production of starch and corn syrup. The comment submitted a copy of an exchange of letters between the Corn Industries Research Foundation and FDA. In a letter dated August 17, 1959, the research foundation described in detail the conditions and levels of use of hydrogen peroxide in the manufacture of corn starch and bleached corn starch. In its response to that letter, FDA confirmed an opinion that had been given orally by an agency official that corn starch and bleached corn starch, among several corn products, were GRAS. From this agency response, the comment inferred that hydrogen peroxide is GRAS when used in the production of such corn products. In support of this conclusion, the comment also submitted a copy of a U.S. patent dated October 15, 1940, that describes the use of between 0.05 to 0.15

percent (on a 100-percent basis) hydrogen peroxide as an antimicrobial agent in the manufacture of thermophile-free starch. The comment stated that thermophile-free starches are those starches that meet specifications of the canning industry. These specifications require that starches be substantially free of thermophilic spores, flat sour spores, thermophilic anaerobic spores, and sulphide spoilage spores.

The comment also reported the use of hydrogen peroxide to reduce the level of sulfur dioxide after the corn steeping and grinding operations in corn refining. (Sulfur dioxide is used to facilitate the separation of the starch and protein components of corn.) The comment stated that the usual level of use of hydrogen peroxide for this purpose was

0.04 percent.

The comment also provided the results of a survey of corn products producers concerning the extent to which hydrogen peroxide is used in the processing of starch. Those producers that responded to the survey reported usage levels ranging from 0.03 to 0.17 percent (on a 100-percent active basis). The comment reported that residual hydrogen peroxide is removed from the starch by washing with potable water and drying in high temperature dryers at intake temperatures of 400 to 500 Fahrenheit (F) and exhaust temperatures in the range of 160 °F to 170 °F.

The comment also reported the use of hydrogen peroxide as a processing aid to reduce sulfur dioxide levels in the production of corn syrup. The comment reported that the sulfur dioxide content of corn syrup during processing is in the range of 0.002 to 0.003 percent. The comment explained that hydrogen peroxide is added to the corn syrup at a level that is 1 to 3 times the sulfur dioxide content but does not exceed 0.15 percent of the corn syrup. The comment stated that the heat used in the evaporation steps in the manufacture of the corn syrup destroys the hydrogen peroxide, thus leaving no peroxide residue. The comment expressed its belief that the information it provided showed that hydrogen peroxide had been used in the processing of starch since the 1930's, and that this use was known by regulatory officials. Therefore, the comment requested that this use of hydrogen peroxide be affirmed as GRAS.

3. Three comments from tea producers reported the use of hydrogen peroxide as a bleaching agent in instant tea. All three comments reported similar processing procedures, i.e., water extraction of tea leaves, concentration

- of the extract, bleaching and polishing of the concentrate, and, finally, heat drying. Bleaching is accomplished by adding hydrogen peroxide at a level of 1 to 3 percent of the concentrated extract. Residual hydrogen peroxide is removed during the evaporation and heat spray drying process. The comment described the use of hydrogen peroxide in instant tea processing as self-limiting because excessive levels of residual hydrogen peroxide results in a product of no commercial value.
- 4. One comment asked that the proposed rule be amended to permit hydrogen peroxide as a bleach for annatto-colored whey. The comment reported that residual hydrogen peroxide is removed from the bleached whey by a potable water wash and spray drying at elevated temperatures. The comment noted that hydrogen peroxide is already affirmed as GRAS as an antimicrobial agent in the processing of modified wheys in § 184.1979 (21 CFR 184.1979). The comment reported that the level of use of hydrogen peroxide as a bleach of annatto-colored whey is approximately the same as the level at which it is used as an antimicrobial agent in modified wheys, i.e., at a level of 0.05 percent.

5. One comment reported the use of hydrogen peroxide as a processing aid to reduce the level of sulfur dioxide in wine used to make wine vinegar. The comment stated that the use of 757 milliliters of an aqueous solution of 35 percent hydrogen peroxide will inactivate 30 parts per million sulfur dioxide in 1,000 gallons of wine, i.e., at a level of 0.02 percent. (The amount of hydrogen peroxide needed to remove sulfur dioxide will vary depending upon the sulfur dioxide content of the wine.) The comment submitted a copy of Alcohol Tax Circular No. 1066, Amendment No. 1, dated June 16, 1950, which authorizes the use of hydrogen peroxide to reduce the sulfur dioxide content of distilling material so long as no hydrogen peroxide remains in the finished product. The comment also submitted a copy of Internal Revenue Ruling 63-331, dated June 19, 1963, which authorizes the use of hydrogen peroxide to facilitate secondary fermentation in the production of champagne and other sparkling wines. The comment also cited a July 1, 1967, Bureau of Alcohol, Tobacco, and Firearms authorization for the use of hydrogen peroxide at a maximum of 200 parts per million to reduce aldehydes in distilling material.

The comment suggested that it is not necessary to include a limitation on the level of addition of hydrogen peroxide for this use because any residual hydrogen peroxide is removed during the acetification, aeration, and pasteurization steps in the production of the wine vinegar.

II. Consideration of GRAS Status of Reported Uses

In the proposal, the agency stated that it was likely that the National Academy of Sciences/National Research Council (NAS/NRC) survey did not report all existing uses of hydrogen peroxide, and that, as a result, some uses of hydrogen peroxide were not included in § 184.1366(c) of the proposed GRAS affirmation regulation (48 FR 52323). The seven comments that FDA received demonstrate that the agency was correct.

In the preamble to the proposal (48 FR 52323), the agency set forth the specific types of information that should be submitted by persons who wanted the agency to consider additional uses of hydrogen peroxide. The agency finds that the seven comments that presented additional uses of this substance have submitted the necessary information to permit the agency to evaluate these uses. The agency has reviewed the use level information, technical effects data, and the processing procedures for each use of hydrogen peroxide cited in the seven comments. Based upon its review, FDA finds that it can affirm most of the uses reported in the comments as GRAS. However, for starch, FDA is affirming as GRAS only the use of hydrogen peroxide as an antimicrobial agent to produce thermophile-free starch and as an agent to remove sulfur dioxide from starch slurry, with a maximum use level of 0.15 percent for these uses. The technical effect associated with the reported use of 0.17 percent hydrogen peroxide in starch processing was not identified. Based on the approximate range of levels reported in the survey and the fact that the reported maximum level in the related use of hydrogen peroxide in corn syrup is 0.15 percent, the agency concludes that a maximum level of 0.15 percent will adequately cover the use of hydrogen peroxide in starch processing.

FDA finds that the food additive regulation on food starch-modified (21 CFR 172.892) already provides for the use of hydrogen peroxide in the bleaching of this type of starch. Therefore, the agency is not modifying the final rule to incorporate this use.

FDA considers it likely that there will be little if any increased exposure to hydrogen peroxide from the uses of this substance that were reported in the comments because (1) each comment described a step in which any residual hydrogen peroxide would be removed or destroyed, and (2) food processors were already using hydrogen peroxide for these uses. Therefore, based on the small increase in exposure and on the agency's review of the data on the safety of hydrogen peroxide, FDA is affirming these uses of hydrogen peroxide as GRAS and is incorporating them in 21 CFR 184.1366(c).

III. Modification of the Regulation

The proposal prescribed a specific method for removing residual hydrogen peroxide for each use of this substance that the agency proposed to affirm as GRAS. Based upon its review of the comments and of the original report from the Select Committee, the agency finds that a number of physical and chemical methods exist that food manufacturers can use to reduce or to eliminate residues of hydrogen peroxide. The agency also finds that many of these methods can be used to reduce the level of residual hydrogen peroxide in a variety of foods.

The agency is concerned that if it attempts to identify specific procedures for reducing hydrogen peroxide residues in specific foods, it may inhibit future innovation in the development of manufacturing procedures for the foods in which hydrogen peroxide is used. For this reason, the agency is deleting the column for limitations or restrictions from the table in paragraph (c) of § 184.1366 and instead is establishing a new paragraph (d) that contains a general requirement that residual hydrogen peroxide is to be removed from food by appropriate physical and chemical processes. Because this general requirement is consistent with the limitations originally proposed for the table in paragraph (c) and merely reflects the fact, as pointed out in the comments, that a number of alternate methods for removing hydrogen peroxide exist, the agency concludes that it is not necessary to seek comments on new paragraph (d).

IV. Environmental and Economic Assessments

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (November 17, 1983; 48 FR 52323). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

List of Subjects

21 CFR Part 182

Food ingredients, Spices and flavorings.

21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 182 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and 5.11.

2. Part 182 is amended:

§ 182.70 [Amended]

a. In § 182.70 Substances migrating from cotton and cotton fabrics used in dry food packaging by removing the entry "Hydrogen peroxide."

§ 182.1366 [Removed]

b. by removing § 182.1366 Hydrogen peroxide.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

4. Part 184 is amended in § 184.1366 by revising paragraphs (c), (d), and (e) to read as follows:

§ 184.1366 Hydrogen peroxide.

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Food	Maximum treatment level in food (percent)	Functional use
Milk, intended for use during the cheesemaking process as permitted in the appropriate standards of identity for cheese and related cheese products under Part 133 of this	0.05	Antimicrobial agent as defined in § 170.3 (o)(2) of this chapter
chapter. Whey, during the preparation of modified whey by	0.04	do
electrodialysis methods. Dried eggs, dried egg whites, and dried egg yolks as in §§ 160.105, 160.145, and 160.185 of this	Amount sufficient for the purpose.	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter
chapter Tripe	do	Bleaching agent
Herring	Amount sufficient for the purpose, (Hydrogen percoide may be in the form of a compound salt, sodium carbonate peroxide). Amount sufficient for the purpose, do	do Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter. Antimicrobial
Sarch	0.15	Antimicrobial agent as defined in \$170.3 (o)(2) of this chapter, to produce thermophile-free starch; Flemove sulfur dioxide from starch sturry following steeping and
Instant lea	Amount sufficient	grinding operations of corn refining. Bleaching agent.
Corn syrup	for the purpose. 0.15	Reduce sulfur dioxide levels in the finished
Colored (annatto)	0.05	corn syrup. Bleaching agent.
cheese whey. Wine vinegar	Amount sufficient for the purpose.	Remove sulfur dioxide from wine prior to fermentation to produce vinegal

Food	Maximum treatment level in food (percent)	Functional use
Emulsifiers containing fatty acid esters.	1.25	Bleaching agent.

(d) Residual hydrogen peroxide is removed by appropriate physical and chemical means during the processing of food where it has been used according to paragraph (c) of this section.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: July 17, 1986.

James W. Swanson,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 17036 Filed 7-29-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 184

[Docket No. 81N-0348]

Benzoyl Peroxide; Affirmation of GRAS Status

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that benzoyl peroxide is generally recognized as safe (GRAS) as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective August 29, 1986. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1157 effective on August 29, 1986.

FOR FURTHER INFORMATION CONTACT:

Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472– 5690.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 1, 1982 (47 FR 43402), FDA published a proposal to affirm that benzoyl peroxide is GRAS for use as a direct human food ingredient. FDA published this proposal in accordance with its announced review of the safety of GRAS and priorsanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the reports of the Select Committee on GRAS Substances (the Select Committee) on benzoyl peroxide

have been made available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents are also available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of benzoyl peroxide, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those prior sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of this ingredient recognized by issuance of an appropriate regulation under Part 181-Prior-Sanctioned Food Ingredients (21 CFR Part 181), or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for benzoyl peroxide were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of this ingredient under conditions different from those set forth in this final rule has been waived.

FDA received three comments in

response to the proposal.

One comment, from a soya products company, supported the regulation as proposed. Thus, no response to that comment is necessary.

The other two comments did not question the agency's tentative determination that the use of benzoyl peroxide is GRAS. However, the comments did request that proposed § 184.1157(c)(2) be amended to include the use of benzoyl peroxide as a substitute for hydrogen peroxide for bleaching annatto-colored whey. Both comments presented published studies on the effectiveness of benzoyl peroxide for this use, as well as a study on the decomposition of benzoyl peroxide in whey.

One of these two comments, in response to a request from FDA, provided supplemental information clarifying the conditions of use of benzoyl peroxide in the manufacture of

whey, including the proposed level of use, the residue level, and the method of analysis for residues of benzoyl peroxide in bleached whey.

FDA has thoroughly reviewed these two comments as well as the supplemental information that was submitted. The agency finds that the use of benzoyl peroxide to bleach annattocolored whey is a new use. FDA has estimated the increase in use of benzoyl peroxide in food that would result from this use. It finds that this use of benzoyl peroxide will result in an increase in dietary exposure to this substance that is so small that it falls within the level that the Select Committee considered to be safe.

This latter finding is based on (1) the Select Committee's conclusion that no evidence in the available information on benzoyl peroxide demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when benzovl peroxide is used at levels that are now current or that might reasonably be expected in the future; (2) the Select Committee's estimate in its reports that the then current per capita level of addition of benzoyl peroxide to food was about 8.5 miligrams per day; (3) the agency's estimate that the per capita level of addition of benzoyl peroxide to food resulting from its use as a bleach for annatto-colored whey would be no more than 0.023 milligram per day; and (4) the Select Committee's finding, supported by the data in the comments to the proposal, that most of the benzoyl peroxide employed as a bleach would be converted to benzoic acid during food processing, and that only traces of residual peroxide would be ingested.

Based on the findings of the Select Committee and on its own review of the data, the agency concludes that it can affirm the use of benzoyl peroxide in food, including its use in whey, as GRAS. The agency is issuing § 184.1157(c)(2) to affirm these uses as GRAS.

The agency has made a minor editorial change in 21 CFR 184.1157(c)(2). The agency reconsidered the proposed language in this section that referred to the use of benzoyl peroxide in milk used in the production of certain cheeses, as specified in the appropriate food standards. Because the proposed language could be considered vague and could be misinterpreted, the agency has revised § 184.1157(c)(2) to list the specific food standards for cheese under which benzoyl peroxide may be used.

The agency has carefully considered the potential environmental effects of this action and has concluded that the

action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the Federal Register of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an environmental assessment under 21 CFR 25.31a(a)(1)

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities. including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 184 is amended as follows:

PART 184-DIRECT FOOD SUBSTANCES AFFIRMED AS **GENERALLY RECOGNIZED AS SAFE**

1. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10 and

2. Part 184 is amended by adding new § 184.1157, to read as follows:

§ 184.1157 Benzoyl peroxide.

- (a) Benzoyl peroxide ((C6H5CO)2O2. CAS Reg. No. 94-36-0) is a colorless, rhombic crystalline solid. It is prepared by reaction of benzoyl chloride, sodium hydroxide, and hydrogen peroxide.
- (b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 35, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.
- (c) In accordance with § 184.1(b)(1). the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:
- (1) The ingredient is used as a bleaching agent in food.
- (2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: flour; milk used for production of Asiago fresh and Asiago soft cheese (§ 133.102), Asiago medium cheese (§ 133.103), Asiago old cheese (§ 133.104), Blue cheese (§ 133.106), Caciocavallo siciliano chesse (§ 133.111), Gorgonzola cheese (§ 133.141), Parmesan and reggiano cheese (§ 133.165), Provolone cheese (§ 133.181), Romano cheese (§ 133.183), and Swiss and emmentaler cheese (§ 133.195) in Part 133 of this chapter; and annatto-colored whey, such that the final bleached product conforms to the descriptions and specifications for whey, concentrated whey, or dried whey in § 184.1979(a) (1), (2), or (3), respectively.
- (d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: July 17, 1986.

James W. Swanson,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-17035 Filed 7-29-86; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 8090]

Income Taxes; Possessions Tax Credit; Definition of Product, Significant Business Presence Test, and Cost Sharing and Profit Split Elections

Correction

In the issue of Friday, June 13, 1986, in the document beginning on page 21518 in the second column, make the following corrections:

§ 1.936-5 [Corrected]

1. On page 21525, in § 1.936–5(a), second column, Example (2), last line, insert "later" after "that".

insert "later" after "that".

2. On page 21530, in § 1.936–5(b)(4), third column, in the eleventh line, "to" should read "with", and in the thirteenth line, "located" should read "allocated".

3. On page 21531, in § 1.936–5(b)(7), third column, eleventh line, "the" should read "that".

§ 1.936-6 [Corrected]

4. On page 21539, in § 1.936-6(b)(1), third column, two lines above Example 3, "titles" should read "tiles".

5. On page 21546, third column, in the FR docket line, "86–13156" should have read "86–13158".

BILLING CODE 1505-01-M

PANAMA CANAL COMMISSION 35 CFR Part 103

General Provisions Governing Vessels

AGENCY: Panama Canal Commission.
ACTION: Interim rule with request for comments.

SUMMARY: The Panama Canal
Commission is amending its regulations
in Title 35, Code of Federal Regulations,
§ 103.8 concerning preference in transit
schedulings and order of transiting
vessels. The changes take into account
the agency's experience with the
Panama Canal Transit Booking System
over the preceding three years and the
corresponding needs of the shipping
community.

EFFECTIVE DATE: The amendments made herein are effective July 30, 1986. Written comments should be submitted on or before August 29, 1986.

ADDRESSES: Comments should be sent to Secretary, Panama Canal Commission. 2000 L Street, NW., Suite 550, Washington, DC. 20036–4996 or Panama Canal Commission, Office of General Counsel, APO Miami, Florida 34011–5000.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Rhode, Jr., Secretary, Panama Canal Commission, telephone: (202) 634–6441 TDD., or Mr. John L. Haines, Jr., General Counsel, telephone in Balboa Heights, Republic of Panama, 011–507–52–7511.

SUPPLEMENTARY INFORMATION: By a document published on March 4, 1983, (48 FR 27406), the Panama Canal Commission adopted a voluntary system by which a limited number of vessels may be assured a timely transit of the Canal, upon payment of a special charge. The purpose of this document is to make several changes to the booking system regulations based on numerous requests from Canal users that the Canal Commission revise the arrival time requirements in the present rules. The changes take into account the need to better serve our customers, without adversely affecting Canal operations.

The present regulations, in § 103.8(f)(1), require that booked vessels which are subject to transit restrictions arrive at a terminus of the Canal by midnight (2400 hours) of the day prior to the intended transit. At present, booked vessels not subject to transit restrictions must arrive prior to noon of the day of the intended transit. This section is being revised to allow both classes of vessels to arrive at a Canal terminus one hour later. Under this revision, restricted vessels must arrive not later than 0100 hours of the day of the transit, and non-restricted vessels must arrive not later than 1300 of the day of the transit.

In addition to the arrival time changes, the agency is revising the rules concerning forfeiture of the booking fee. The present rules provide that vessel which does not arrive by the specified arrival time forfeits the booking fee unless its arrival has been delayed by force majeure. The term force majeure has caused some confusion in the past, and accordingly, the grounds for waiving a forfeiture are being rephrased. Under the revised rule no forfeiture will occur, if the vessel's arrival is delayed by a natural event or major proportions, not caused by the intervention of man, which could not reasonably be predicted in advance. Heavy seas are not considered such a major natural event.

The amendment concerning the arrival times is a *de minimis* change that liberalizes current rules for booked vessels. The revision of the *force majeure* rule is not substantive, but is intended to clarify the rule. Accordingly,

these amendments are effective upon publication of this notice, but comments concerning these revisions are invited and will be carefully considered.

The Commission has determined that this rule does not constitute a major rule within the meaning of Executive Order 12291 dated February 17, 1982 (47 FR 13193). The bases for that determination are, first, that the rule, when implemented would not have an annual effect on the economy of \$100 million or more per year, and secondly, that the rule would not result in a major increase in costs or prices for consumers, individual industries, local governmental agencies or geographic regions. Further, the agency has determined that implementation of the rule will have no adverse effect on competition, employment, investment, productivity, innovation or the ability of United States based enterprises to compete with foreign-based enterprises in domestic or export markets.

Finally, the Commission has determined that this rule in not subject to the requirements of sections 603 and 604 of Title 5, United States Code, in that its promulgation will not have a significant impact on a substantial number of small entities, and the Administrator of the Commission so certifies pursuant to 5 U.S.C. 605(b).

List of Subjects in 35 CFR Part 103

Panama Canal, Vessels, Booking system, Navigation (water).

PART 103—GENERAL PROVISIONS GOVERNING VESSELS

Accordingly, 35 CFR Part 103 is amended as follows:

1. The authority citation for Part 103 continues to read as follows:

Authority: 22 U.S.C. 3811, E.O. 12215, 45 FR 36043 and 44 U.S.C. 3501.

2. Section 103.8(f)(1) is revised to read as follows:

§ 103.8 Preference in the transit schedule; order of transiting vessels.

(f) Penalties. (1) When a vessel that is subject to transit restrictions (e.g., clearcut; clear-cut daylight), has been booked for transit and does not arrive at a terminus of the Canal by 0100 of the day of the intended transit, the booking fee will be forefeited. Similarly, the fee will be forfeited if a booked vessel that is not subject to such transit restrictions does not arrive by 1300 hours of the day of the intended transit. In either case, upon arrival, the vessel will be placed in the regular transit schedule. This forfeiture will not occur if late arrival is

due to humanitarian reasons or a
natural event of major proportions,
which is not caused by the intervention
of man, and which could not be
reasonably predicted in advance. The
booking fee will also be forfeited if the
vessel arrives on time but cannot or, at
the operator's election, does not, transit
as scheduled when the agency is ready
to proceed. In these latter cases, the
Canal authorities shall have discretion
to waive the forfeiture where it is
established that the delay was due to
external causes that the vessel operator
could not reasonably have anticipated.

* * * * *

Dated: July 16, 1986.

D.P. McAuliffe,

Administrator, Panama Canal Commission.

[FR Doc. 86–17020 Filed 7–29–86; 8:45 am]

BILLING CODE 3640-04-M

Proposed Rules

Federal Register

Vol. 51, No. 146

Wednesday, July 30, 1986

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 400

[Docket No. 3366S]

General Administrative Regulations-Standards for Approval; Agency Sales and Service Contract

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) hereby proposes to revise and reissue the Standards for Approval; Agency Sales and Service Contract as contained in 7 CFR Part 400-Subpart C. The intended effect of this rule is to: (1) Require the Contractor to maintain a minimum level of business of \$500,000, effective July 1, 1987; (2) require all Contractors to maintain a minimum of 25 active contractor representatives; (3) remove the clause which allows certain non-licensed agents to sell and service crop insurance; (4) add sections specifying the terms of the contract; and (5) add a definition for the term "Sales". These regulations set forth requirements which must be met in order to be eligible for an Agency Sales and Service Contract with FCIC. The authority for the promulgation of this rule is contained in the Federal Crop Insurance Act, as amended.

DATE: Written comments, data, and opinions on this proposed rule must be submitted not later than August 29, 1986, to be sure of consideration.

ADDRESS: Written comments on this proposed rule should be sent to the Office of the Manager, Federal Crop Insurance Corporation, Room 4096, South Building, U.S. Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC, 20250, telephone (202) 447–3325. SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Departmental Regulation 1512–1. This action constitutes a review as to the need, currency, clarity, and effectiveness of these regulations under those procedures. The sunset review date established for these regulations is June 1, 1991.

E. Ray Fosse, Manger, FCIC, (1) has determined that this action is not a major rule as defined by Executive Order 12291 because is will not result in: (a) an annual effect on the economy of \$100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and (2) certifies that this action will not increase the federal paperwork burden for individuals, small businesses, and other persons.

This action is exempt from the provisions of the Regulatory Flexibility Act; therefore, no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR 3015, Subpart V, published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

The principal changes in the Standards for Approval; Agency Sales and Service Contract, are:

1. § 400.28—Add a provision to require a Contractor to maintain a minimum level of business of \$500,000 in order to continue participation in the Agency Sales and Service Contract, effective July 1, 1987. This will allow FCIC to determine if the participating companies are of sufficient size and

strength in meeting the requirements of the program.

Add a definition for the term "Sales" to clarify its use throughout the standards.

2. § 400.33—Require all Sales and Service Contractors to maintain a minimum of 25 licensed and certified contractor representatives which meet the standards of approval set out herein.

Remove the clause which allowed certain non-licensed agents to sell crop insurance. This provision is no longer applicable.

3. §§ 400.34 and 35—Add sections to cover the execution and termination of the Contract and the eligibility requirements which must be met by a Contractor for continued participation.

FCIC is soliciting public comments on this proposed rule for 30 days after publication in the Federal Register. Written comments will be available for public inspection in the Office of the Manager, Federal Crop Insurance Corporation, Room 4906, South Building, U.S. Department of Agriculture, Washington, DC 20250, during regular business hours, Monday through Friday.

List of Subjects in 7 CFR Part 400

Crop insurance; Agency sales and service contract; Standards for approval.

Proposed Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 et seq.), the Federal Crop Insurance Corporation hereby proposes to revise and reissue 7 CFR Part 400, Subpart C, General Administrative Regulations; Agency Sales and Service Contract—Standards for Approval, to read as follows:

PART 400—GENERAL ADMINISTRATIVE REGULATIONS

Subpart C—Agency Sales and Service Contract—Standards for Approval

Sec

400.27 Applicability of standards.

400.28 Definitions

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400.31 Denial or termination of contract and administrative reassignment of business.

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400.35 The Agency Sales and Service Contract for the year July 1, 1987 through June 30, 1988.

400.36 OMB control numbers.

Authority: Secs. 506, 516, Pub. L. 75-430, 52 Stat. 73, 77, as amended (7 U.S.C. 1506, 1516).

Subpart C—Agency Sales and Service Contract—Standards for Approval

§ 400.27 Applicability of standards.

The Standards contained herein must be met in order for an entity to be a contractor under an Agency Sales and Service Contract (Contract).

§ 400.28 Definitions.

For the purpose of these Standards:

- (a) "Agency Sales and Service Contract" means the contract between the Federal Crop Insurance Corporation (Corporation) and a private entity (Contractor) for the purpose of selling and servicing Federal Crop Insurance policies.
- (b) "CPA" means a Certified Public Accountant who is licensed as such by the State in which the CPA practices.
- (c) "CPA Audit" means a professional examination in accordance with generally accepted auditing standards by a CPA of a Financial Statement on the basis of which the CPA expresses an independent professional opinion respecting the fairness of presentation of the Financial Statements.
- (d) "Current Assets" means cash and other assets that are reasonably expected to be realized in cash or sold or consumed during the normal operation cycle of the business or within one year if the operation cycle is shorter than one year.
- (e) "Current Liabilities" means those liabilities expected to be satisfied by either the use of assets classified as current in the same balance sheet, or the creation of other current liabilities, or those expected to be satisfied within a relatively short period of time, usually one year.
- (f) "Financial Statement" means the documents submitted to the Corporation by a private entity which reflects the financial position, result of operations, and change in financial position of the private entity.
- (g) "Minimum level of business" means that a company under an Agency Sales and Service Contract must be able to show sales of crop insurance contracts of at least \$500,000 as measured by base premium generated for the period July 1 through June 30 immediately prior to the contract year.
- (h) "Sales" means new applications and renewals of FCIC policies.

§ 400.29 Certification of submission.

An entity desiring to be a contractor shall submit to the Corporation its latest financial statement certified by a CPA or, if such financial statement is not available, its latest financial statement accompanied by a certification of the Chief Executive Officer and Treasurer that said statement fairly represents its financial condition on the date of submission to the Corporation. If a financial statement certified by the Chief Executive Officer and Treasurer is submitted, CPA audited financial statements must be submitted if subsequently available.

§ 400.30 Notification of deviation from standards.

A Contractor shall advise the Corporation immediately if the Contractor deviates from the requirements of these standards. The Corporation may require the Contractor to show compliance with these standards during the contract year if the Corporation determines that such submission is necessary.

§ 400.31 Denial or termination of contract and administrative reassignment of business.

Non-compliance with these standards shall be grounds for: (a) The denial of a Contract or (b) termination of an existing Contract. In the event of termination of the Contract, all crop insurance policies of the Corporation sold by the Contractor and all business pertaining thereto may be assumed by the Corporation and may be administratively reassigned by or at the direction of the Corporation to another Contractor.

§ 400.32 Financial Qualifications for acceptability.

The financial statements of an entity must show a positive net worth and the ability of the entity to meet current liabilities by the use of current assets.

§ 400.33 Representative licensing and certification.

A Contractor must maintain twentyfive (25) licensed and certified Contractor representatives. A Contractor's representative who sells and services FCIC policies or represents the Contractor in sales or servicing of such policies:

(a) Must hold a current license issued by each State in which the representative sells or solicits business which license authorizes the sales of insurance in at least one of the following

- (1) multiple peril crop insurance;
- (2) crop hail insurance;
- (3) casualty insurance;

- (4) property insurance; or
- (5) liability insurance; and
- (b) Must be certified by FCIC for each crop for which the representative sells or services FCIC insurance.

§ 400.34 Term of the contract.

- (a) The term of the 1987 Agency Sales and Service Contract shall commence on October 1, 1986 or when properly executed by the Contractor and the Corporation and shall terminate on June 30, 1987. The contract may be terminated by the Corporation on thirty (30) days written notice if the Contractor breaches any of the provisions of the contract. The contract may be terminated by either the Corporation or the Contractor on sixty (60) days written notice by one party to the other for any reason.
- (b) Unless the contract has been previously terminated, the Contractor shall be eligible during the month of June, 1987 to receive another Agency Sales and Service Contract offered by the Corporation for the period commencing July 1, 1987 and ending June 30, 1988 provided:
- (1) Contractor is in compliance with the Standards of Approval as promulgated by the Corporation, and in effect on June 30, 1987, setting forth the Contractor's eligibility requirements;
- (2) Contractor maintains a minimum level of business (unless the Contractor was not a Contractor during the prior period);
- (3) Contractor has not breached or violated the provisions of the current contract; and
- (4) Contractor is not under suspension as provided in the current contract.

§ 400.35 The Agency Sales and Service Contract for the year July 1, 1987 through June 30, 1988.

If an Agency Sales and Service
Contract is offered by the Corporation
for the period July 1, 1987 through June
30, 1988, any Contractor who receives
such a contract will be required to
maintain a minimum level of business in
order to be eligible for an Agency Sales
and Service Contract which may be
offered by the Corporation the following
year.

§ 400.36 OMB control numbers.

OMB control numbers are contained in Subpart H of Part 400, Title 7 CFR.

Done in Washington, DC, on July 14, 1986. E. Ray Fosse,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 86-17071 Filed 7-29-86; 8:45 am] BILLING CODE 3410-08-M

Agricultural Marketing Service

7 CFR Part 1036

[Docket No. A0-179-A49]

Milk In the Eastern Ohlo-Western Pennsylvania Marketing Area; Partial Decision on Proposed Amendments to Tentative Marketing Agreement and to Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This partial decision adopts certain changes in the Eastern Ohio-Western Pennsylvania milk order based on industry proposals considered at a public hearing held August 7-8, 1985. The changes would: 1. Reduce the pooling requirements for cooperative balancing plants; 2. Permit the Director of the Diary Division to adjust the pooling standards for pool supply plants and cooperative balancing plants when temporary aberrations occur in the market's supply-demand conditions; and 3. Provide handlers more flexibility in moving milk directly from producer farms to nonpool manufacturing plants. The changes are needed to reflect current marketing conditions and to assure orderly marketing in the area. A referendum will be conducted to determine whether producers who supplied milk during May 1986 favor the issuance of the order.

FOR FURTHER INFORMATION CONTACT:
Maurice M. Martin, Marketing
Specialist, Dairy Division, Agricultural
Marketing Service, United States
Department of Agriculture, Washington,
DC 20250, (202) 477-7311.

SUPPLEMENTARY INFORMATION: This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Order 12291.

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires the Agency to examine the impact of a proposed rule on small entities. Pursuant to 5 U.S.C. 605(b), the Administrator of the Agricultural Marketing Service has certified that this action will not have a significant economic impact on a substantial number of small entities. The proposed amendments modify the pooling standards and the diversion provisions of the Eastern Ohio-Western Pennsylvania milk order to make it conform more closely to current economic conditions that exist in the market place. The principal changed marketing condition involves the market's supply-demand relationship for

milk, exemplified in a ten-percent decrease in the market's Class I utilization since the present provisions were adopted. Reflection of this changed marketing condition through the amendments herein should lesson the regulatory impact of the order adopted on regulated handlers.

The hearing notice specifically invited interested persons to present evidence concerning the probable regulatory and informational impact of the proposals on small businesses. This decision contains an economic analysis and takes into consideration the impact of the proposed changes in regulation on the diary industry, including to the extent necessary, the impact of such changes on small businesses. Although this decision is not identical to a regulatory flexibility analysis, it is based on the record evidence obtained at a public hearing and therefore serves the same purpose.

Prior documents in this proceeding: Notice of Hearing: Issued July 19, 1985; published July 24, 1985 (50 FR 30204).

Suspension Order: Issued September 4, 1985; published September 10, 1985 (50 FR 36865).

Partial Recommended Decision: Issued February 14, 1986; published February 21, 1986 (51 FR 6245).

Preliminary Statement

A public hearing was held upon proposed amendments to the marketing agreement and the order regulating the handling of milk in the Eastern Ohio-Western Pennsylvania marketing area. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), at Strongsville, Ohio, on August 7–8, 1985.

Upon the basis of the evidence introduced at the hearing and the record thereof, the Deputy Administrator, Marketing Programs, on February 14, 1986, filed with the Hearing Clerk, United States Department of Agriculture, a recommended decision containing notice of the opportunity to file written exceptions thereto.

The material issues, findings and conclusions, rulings and general findings of the recommended decision are hereby approved and adopted and are set forth in full herein, modified to the extent that a new paragraph has been added at the end of issue 1(b) and at the end of issue

The material issues on the record of hearing relate to:

1. Pool plant qualifications.

2. Diversions to nonpool plants.

3. Location adjustments.

This decision deals only with issues 1 and 2. The remaining issue 3 is reserved for a later decision.

Findings and Conclusions

1. Pool plant qualifications (a) Pooling standards for balancing plants. Several modifications should be made in the pooling standards for any non-distributing plant operated by a cooperative association as a balancing plant for the regulated market.

First, the minimum monthly delivery requirement to pool distributing plants to qualify a balancing plant as a pool plant under the order should be reduced to 35 percent of a cooperative association's total receipts. The delivery requirement to pool distributing plants can be met either by direct delivery from member producers' farms or by transfer from such cooperative's plant(s).

Second, the delivery requirement can be met on the basis of the cooperative's deliveries to pool distributing plants during the current month or based on such deliveries during the preceding 12month period ending with the current month.

Third, credit would be given in meeting the delivery requirement to a cooperative's shipments to nonpool plants so long as such shipments are not made on an agreed-upon Class II or Class III basis.

Presently, the order provides that a cooperative can attain pool status for its balancing plant(s) if during the month the quantity of fluid milk products either shipped to pool distributing plants from the cooperative's plants or directly delivered to pool distributing plants from the farms of cooperative producer members is not less than 65 percent in any month of September through April, and not less than 50 percent in any other month of the cooperative association members' producer milk.

The principal cooperative in the market, Milk Marketing Inc. (MMI). proposed that the pooling standards for balancing plants operated by cooperatives be reduced from 65 percent in September through April and 50 percent in any other month to 35 percent for each month. As proposed, the delivery requirement could be met either on a monthly basis or on the basis of deliveries over the preceding 12 months. The cooperative also proposed that qualifying deliveries would include those that are made to nonpool plants when a Class II or III classification is not requested.

MMI currently operates two plants under the order which are qualified as

pool supply plants. One plant, in Orrville, Ohio, manufactures dairy products and the other plant, in Greensburg, Pennsylvania, is a receiving station. The cooperative's spokesman stated that these plants balance most of the market's daily and seasonal milk supplies. Based on data presented at the hearing by the proponent cooperative, the amount of milk MMI delivered to pool distributing plants in 1983 expressed as a percent of its total supply of producer-member milk ranged from a high of 50.45 percent in January to a low of 32.64 percent in June. The same comparison for 1984 revealed that a high of 51.35 percent was delivered in November and a low of 33.16 percent was delivered in June.

Daily balancing is reflected in figures for the cooperative's Orrville plant. During November and December 1984, when bottling needs were greatest on certain weekdays, receipts at the plant were relatively low, and often no milk was received. However, on weekends and holidays the plant received milk in excess of 1 million pounds per day.

The spokesman pointed out that MMI's plants have been pooled as supply plants under the order, even though it is apparent that they operate as balancing plants, because the total delivery requirements of the order for cooperative balancing plants are unrealistic in terms of current supplydemand conditions. However, he added that the 40 percent shipping requirement for pool supply plants during each month of September through February in the past has caused MMI to make unnecessary and uneconomic shipments to distributing plants in order to pool all of its member milk. This, he said, is not only costly, but it also reduces milk quality. The spokesman emphasized that relaxing the pooling standards for balancing plants as proposed would enable the cooperative to pool all of its member milk regularly associated with the market on an efficient basis.

The National Farmers Organization (NFO), also proposed that the pooling standards for balancing plants operated by cooperatives be reduced. However, its proposal would reduce the standards from the present levels to 40 percent each month. Additionally, NFO proposed that the delivery requirement could be met either on the basis of deliveries for the current month or during the preceding 12-month period ending with the current month. The spokesman stated that since the intent and operation of NFO's proposal is very similar to what MMI proposed, NFO could accept the proposed lower 35percent delivery requirement.

The present delivery requirements for pool balancing plants were established in 1972, reflecting approximately the Class I utilization percentage of the milk of MMI members at fluid plants and also the market's Class I utilization percentage. However, the 65-percent delivery requirement for each month of September through April and the 50percent requirement for the remaining months have proved to be unattainable rates in qualifying the two balancing plants operated by MMI. In fact, not one plant operated by a cooperative since the balancing plant provisions were implemented has ever qualified pursuant to these requirements. Instead, MMI has qualified its two plants as pool supply plants.

The record establishes that marketing conditions have changed significantly since the present pooling standards for balancing plants were established in 1972. Data for the market indicates a significant change has occurred in the supply-demand relationship for milk associated with the market since that time. For example, during the 12-year period from 1972 to 1984, producer milk receipts increased from 3.32 billion pounds in 1972 to 3.67 billion pounds in 1984 (an 11 percent increase).

During this same period, producer milk classified as Class I milk declined from 2.15 billion pounds in 1972 to 2.02 billion pounds in 1984 (a 6 percent decrease). Consequently, the market's Class I utilization percentage of producer milk has decreased substantially since 1972 (from 65 percent in 1972 to 55 percent in 1984). These data clearly indicate significant changes in the market's supply-demand relationship for milk since the present delivery requirement for balancing plants was adopted in 1972.

Another changed marketing condition described on the record supporting a reduction in the delivery requirements for a balancing plant concerns the substantial change in the market's fluid milk processing operations. Not only has there been a substantial reduction in the number of pool distributing plants on the market but also the relatively few remaining operations have become large, specialized distributing plants that process fluid milk not more than five days per week. As a result, the day-today fluid milk requirements at such specialized plants fluctuate widely. An exhibit of proponent MMI clearly demonstrated the wide day-to-day fluctuations in fluid milk requirements of distributing plants. On the heavy bottling days of the week, such plants need significant quantities of milk for their fluid operations, while on weekends, the plants are closed and no milk is received. This pattern of fluctuating demand for milk at these specialized distributing plants requires larger quantities of reserve milk than when such plants were less specialized and operated six or seven days per week.

To accommodate the pooling of the increased volume of reserve milk supplies, it has been necessary to suspend various pooling provisions of the order during the 1983–1985 period. Such suspensions have involved pool supply plant shipping percentages, balancing plant delivery requirements, and diversion limits. The suspension of these several provisions enabled MMI to move its total milk supply associated with the market on an efficient basis and maintain pool status for its two balancing plants.

The record establishes that at other times in the absence of any suspension MMI had to make inefficient movements of milk to other pool plants solely for the purpose of pooling its two balancing plants and the milk of member producers who have regularly supplied the fluid needs of the market. When this occurred, it significantly increased milk transportation and hauling costs. Such inefficient marketing practices can be avoided by reducing the order's pooling requirements for balancing plants.

In view of the significance of the changed marketing conditions described above, lowering the minimum delivery requirement for balancing plants operated by a cooperative association will permit a cooperative to serve the fluid needs of the market in an efficient manner. It will likewise permit a cooperative to perform needed balancing functions for the market without causing inefficient deliveries of milk merely for the purpose of meeting the pooling requirements of the order. The proposed 35 percent delivery requirement will best accomplish these results under the market's current supply-demand conditions and in terms of the principal cooperative's market participation in performing the balancing function.

As noted previously, a cooperative should be able to meet the requirement for certain minimum deliveries to pool distributing plants not only on the basis of such deliveries during the current month but also on the basis of deliveries during the preceding 12-month period. The 12-month rolling average concept was proposed by both MMI and NFO. It

¹ Official notice is taken of the 1973–1984 annual summaries of "Federal Milk Order Statistics" published by the Dairy Division, Agricultural Marketing Service, USDA.

is needed to offset the potentially disruptive impact of a significant shortterm change in marketing conditions on a cooperative's ability to qualify its balancing plant(s) for pooling. Allowing a cooperative such flexibility will assist in maintaining orderly marketing conditions for the regulated area.

In meeting the delivery requirement, a cooperative should receive credit on shipments to nonpool plants that are not made on an agreed-upon Class II or Class III basis. Shipments to another market for Class I purposes would benefit producers in this market since such shipments would enhance total pool proceeds. Not to count such shipments in meeting the delivery requirements could discourage such shipments, when in fact, such shipments may be needed in other markets.

A producer supplying an Order 36 pool plant testified in opposition to the proposals on the basis that their effect would be to facilitate the pooling of additional milk on the market with the consequences of reducing producer returns. A reduction in the delivery requirements for member producer milk will not, in any substantive way, provide the opportunity to pool additional milk not already associated

with the market.

Although the handler did not testify at the hearing, a proprietary handler, in its post-hearing brief, opposed the proposals to relax the pool balancing plant provisions. It was the handler's position that the record evidence does not support these proposals. However, the record evidence developed in this proceeding does not support the position of the handler. To the contrary, the record establishes, as described previously, that relaxing the pooling standards for a balancing plant operated by a cooperative is necessary for the maintenance of orderly marketing.

(b) Temporary revision of pooling standards. The order should be amended to provide that the Director of the Dairy Division may increase or decrease the supply plant shipping percentage and the delivery percentages for qualifying a balancing plant operated by a cooperative association when a determination is made that additional supplies are needed at distributing plants or to prevent uneconomic deliveries for pooling purposes. The adjustment should be limited to 10

percentage points.

Before making any revision, the Director should investigate the need for revision, either on the Director's own initiative or at the request of interested persons. If the investigation shows that a revision may be appropriate, the Director should issue a notice stating

that a temporary revision of the shipping standards is being considered and inviting interested persons to comment

on the proposed revision.

MMI proposed that the Director of the Dairy Division be given the authority to increase or decrease by up to 10 percentage points both the supply plant shipping percentages and the pooling standards for balancing plants operated by cooperatives if the Director finds that such revisions are necessary to obtain needed shipments or to prevent uneconomic shipments. The cooperative proposed further that before making such a finding, the Director shall investigate the need for revision either on the Director's own initiative or at the request of interested persons. If the investigation shows that a revision might be appropriate, the Director shall issue a notice which states that revision is being considered and invite data, views, or arguments in favor of or in opposition to the proposed revision. At the hearing, MMI modified the proposal to apply the revision only to pool balancing plants.

NFO also proposed flexible performance requirement percentages for supply plants and cooperative balancing plants that could be adjusted monthly in multiples of five percentage points. The maximum adjustment in such requirements, as proposed, would be the lesser of the supply plant and balancing plant requirements or the average non-Class I utilization percentage for the previous 12 months. Further, NFO proposed that the Secretary may adjust the requirements for a period not to exceed 6 months with increases from previous adjustments being made prior to the month for which

they are effective.

There was no opposition to the

proposals at the hearing.

The record of the hearing suggests the possibility that an emergency situation affecting the market's supply-demand situation could develop for a short time which would warrant an immediate adjustment (up or down) for either type of plant. Under the current order provisions, a change in a pool plant's performance requirements can be made only through a time-consuming amendment proceeding or by suspension. Although a suspension action can be accomplished relatively quickly, it is limited because of procedural requirements to relaxing rather than increasing performance requirements. Inclusion of a provision to adjust temporarily supply plant shipping percentages and the delivery requirement percentages that a cooperative must meet in qualifying a balancing plant will enhance the ability

of the order to deal with short emergency situations on a timely basis.

The limited modification of the delivery requirements for both supply plants and cooperative balancing plants by the Director of the Dairy Division, as provided herein, would permit downward and upward changes to be made. Thus, the shipping percentages could be adapted to temporary aberrations in supply and demand. Should some unforeseen circumstance temporarily alter the relationship of supplies to sales in such a way that a temporary increase in shipping percentages is necessary to associate adequate supplies of milk with fluid use outlets in the market, the Director would have the authority to temporarily modify the shipping standards upward. Similarly, the Director may temporarily adjust the standards downward in order to prevent uneconomic shipments made solely for pooling purposes. The provisions provided herein for temporary changes in the shipping percentages will provide a desirable degree of flexibility to augment both the pooling provision for supply plants and the revised performance requirements for cooperative balancing plants.

The maximum adjustment adopted herein, which is limited to 10 percentage points, is somewhat less than what was proposed by NFO. However, past experience in the market does not indicate that there would be occasions when a temporary aberration in the supply-demand situation of distributing plants would warrant adjusting the shipping percentages for supply plants and the revised performance requirements for balancing plants beyond 10 percentage points. Accordingly, limiting such adjustment to 10 percentage points is appropriate under the market's current marketing

An exception to the recommended decision filed by MMI pointed out that reference to a limit on the time period that an adjustment to the delivery requirement made by the Director of the Dairy Division can be effective was omitted from the language definding the term "pool plant." As with suspension actions, it is implied that a revision to an order is made on a temporary basis to solve a temporary problem. The Director should be allowed to decide, on a caseby-case basis, the time needed to avoid disruptive marketing conditions caused by temporary aberrations. If a problem were to continue, then serious consideration would be given to holding an amendatory hearing to permanently change an order provision. Therefore, MMI's exception is denied on the basis

that setting a time period for such an action is irrelevant.

2. Diversions to nonpool plants. Rules concerning the diversion of producer milk from pool plants to nonpool plants should be modified as follows:

(a) The limit on the aggregate quantity of milk that may be diverted to nonpool plants by a handler during certain months should be 40 percent of a handler's producer milk, i.e., the quantity delivered to or diverted from pool plants.

(b) March and December should be eliminated as months during which the limit on diversions to nonpool plants

applies.

Presently, the order limits the total amount of milk that cooperatives or other handlers may divert to nonpool plants to 40 percent during the months of September through March of the total quantity of producer milk physically received at a pool plant(s) during the month. Determining diversion limitations on the alternative basis of allowing the same number of days production of an individual producer to be diverted that is actually delivered to a pool plant should be continued without any change

Both MMI and NFO proposed that the limitation on the aggregate amount of producer milk that cooperative associations or other handlers may divert be expanded from an amount equivalent to 40 percent the quantities physically received at pool plants to an amount equivalent to 40 percent of the total producer milk supply of the handler. In addition, NFO proposed that the month during which a handler may divert producer milk without limit to nonpool plants be extended from April through August to include March and December. There was no opposition to the proposals at the hearing.

The main thrust of proponents' arguments in support of their proposals was that in light of the market's current supply-demand conditions, the diversion limits are too restrictive and cause handlers to make uneconomic shipments of milk solely for the purpose for pooling all of the milk that historically has been associated with the market. They stated that such shipments are not only costly, but also reduce the quality of the milk because of the extra pumping and handling involved. Both spokesmen believe that adoption of the proposed changes to the diversion provisions will eliminate inefficient movements of reserve milk supplies while maintaining an adequate supply of milk for fluid purposes.

Limiting the total amount of milk that a handler may divert to a quantity equivalent to 40 percent of the producer milk physically received at a pool plant amounts to a limit of about 29 percent of a handler's total supply of producer milk. This actual diversion limit is too stringent in view of the market's Class I use of producer milk. For instance, over the past 3 years Class I utilization during the months when diversion limits apply has rarely exceeded 60 percent. Furthermore, expectations are that future increases in milk production will exceed any increases in Class I use.

In computing a handler's diversion allowance, the base to which the diversion percentage applies should include the amount of producer milk delivered to pool plants plus the amount diverted from such plants. This change will increase the amount of milk a handler may divert to nonpool plants from about 29 to 40 percent of a handler's total receipts of producer milk. Such an increase should permit handlers adequate flexibility to operate more efficiently. They will be able to move all of the milk not needed at pool plants for fluid purposes directly from the farm to a manufacturing outlet rather than delivering the milk first to a pool plant and then transferring it to a nonpool manufacturing plant. Such efficient movement of milk promotes orderly

NFO proposed that the change in computing diversion allowances apply to cooperatives only. However, it is appropriate to relax the corresponding diversion limit for pool plant operators also, as proposed by MMI. Considering the market's supply-demand situation, proprietary handlers would likely need less-restrictive diversion limits as much as cooperative associations. Under the revisions adopted herein, both proprietary operators and cooperative associations will be subject to the same limitation on diversions to nonpool

As noted previously, NFO also proposed that diversion limitations not apply during the months of December and March. The spokesman stated that in March, Class I utilization usually declines substantially from that of the preceding month (February). Thus, it becomes difficult to maintain pool status for their members' milk. In December, the problem, as stated by the spokesman, stems from the erratic demand for milk at fluid plants on certain days within the month because of the holiday season.

Data contained in the record indicate that there is a seasonal buildup in producer receipts beginning in March. For example, producer receipts on a daily basis for the four-year period. 1982-85, increased an average of 3.1 percent in March over those for

February. During this same period, Class I utilization in March increased only an average of 0.6 percent over February. Consequently, there are substantial quantities of reserve milk on the market in March that must be moved to manufacturing plants. In such circumstances, continuance of diversion limitations for March could adversely affect the orderly and efficient disposition of milk not needed at pool plants for fluid purposes. Accoridnely, the months during which a handler may divert producer milk to nonpool manufacturing plants should be extended from the period April-August to include March. Likewise, because of the erratic daily demand patten for milk at fluid plants during December due to the holiday season and school closings. December should be eliminated as a month in which diversion limitations apply.

In a post-hearing brief, the same proprietary handler who opposed any change in the performance standards for a cooperative balancing plant objected to any revision of the order's present diversion rules. No significant basis was provided in the handler's brief to warrant not revising the diversion provisions as described above.

Rulings on Proposed Findings and Conclusions

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions, and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

General Findings

The findings and determinations hereinafter set forth supplement those that were made when the Eastern Ohio-Western Pennsylvania order was first issued and when it was amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

- (a) The tentative marketing agreement and the order, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;
- (b) The parity prices of milk as determined pursuant to section 2 of the

Act are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the marketing area, and the minimum prices specified in the tentative marketing agreement and the order, as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(c) The tentative marketing agreement and order, as hereby proposed to be amended, will regulate the handling of milk in the same manner as, and will be applicable only to persons in the respective classes of industrial and commercial activity specified in, a marketing agreement upon which a hearing has been held.

Rulings on Exceptions

In arriving at the findings and conclusions, and the regulatory provisions of this decision, each of the exceptions received was carefully and fully considered in conjunction with the record evidence. To the extent that the findings and conclusions and the regulatory provisions of this decision are at variance with any of the exceptions, such exceptions are hereby overruled for the reasons previously stated in this decision.

Marketing Agreement and Order

Annexed hereto and made a part hereof are two documents, a Marketing Agreement regulating the handling of milk, and an ORDER amending the order regulating the handling of milk in the Eastern Ohio-Western Pennsylvania marketing area, which have been decided upon as the detailed and appropriate means of effectuating the foregoing conclusions.

It is hereby ordered. That this entire decision and the two documents annexted hereto be published in the Federal Register. The regulatory provisions of the marketing agreement are identical with those contained in the order as hereby proposed to be amended by the attached order which is published with this decision.

Referendum Order to Determine Producer Approval: Determination of Representative Period; and Designation of Referendum Agent

It is hereby directed that a referendum be conducted and completed on or before the 25th day from the date this decision is issued, in accordance with the procedure for the conduct of referenda (7 CFR 900.300 et seq.), to determine whether the issuance of the attached order as amended and as hereby proposed to be amended, regulating the handling of milk in the Eastern Ohio-Western Pennsylvania marketing area is approved or favored by producers, as defined under the terms of the order (as amended and as hereby proposed to be amended), who during such representative period were engaged in the production of milk for sale within the Eastern Ohio-Western Pennsylvania marketing area.

The representative period for the conduct of such referendum is hereby determined to be May 1986.

The agent of the Secretary to conduct such referendum is hereby designated to be C. Mack Endsley.

List of Subjects in 7 CFR Part 1036

Milk marketing orders, Milk, Dairy products

Signed at Washington, DC, on July 24, 1986. Karen K. Darling,

Deputy Assistant Secretary, Marketing & Inspection Services.

Order ² Amending the Order Regulating the Handling of Milk in the Eastern Ohio-Western Pennsylvania Marketing Area

Findings and Determinations

The findings and determinations hereinafter set forth supplement those that were made when the order was first issued and when it was amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) Findings. A public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order regulating the handling of milk in the Eastern Ohio-Western Pennsylvania marketing area. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et. seq.), and the applicable rules of practice and procedure (7 CFR Part 900).

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said order as hereby amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions

which affect market supply and demand for milk in the said marketing area; and the minimum prices specified in the order as hereby amended are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(3) The said order as hereby amended regulates the handling of milk in the same manner as, and is applicable only to persons in the respective classes of industrial or commercial activity specified in, a marketing agreement upon which a hearing has been held.

Order Relative to Handling

It is therefore ordered that on and after the effective date hereof, the handling of milk in the Eastern Ohio-Western Pennslyvania marketing area shall be in conformity to and in compliance with the terms and conditions of the order, as amended, and as hereby amended, as follows:

The provisions of the proposed marketing agreement and order amending the order contained in the recommended decision issued by the Deputy Administrator, Marketing Programs, on February 14, 1986 and published in the Federal Register on February 21, 1986 (51 FR 6245), shall be and are the terms and provisions of this order, amending the order, and are set forth in full herein.

PART 1036—MILK IN THE EASTERN OHIO-WESTERN PENNSYLVANIA MARKETING AREA

1. The authority citation for Part 1036 continues to read as follows:

Authority: Secs. 1–19, 48 Stat 31, as amended (7 U.S.C. 601–674).

Section 1036.7 is amended by revising paragraph (d) and adding a new paragraph (f) to read as follows:

§ 1036.7 Pool plant.

- (d) A plant operated by a cooperative association if, during the month, 35 percent or more of the producer milk of members of the association is delivered to a distributing pool plant(s) or to a nonpool plant(s) when a Class II or Class III classification is not requested. Deliveries for qualification purposes may be made directly from the farm or by transfer from such association's plant, subject to the following conditions:
- The cooperative requests pool status for such plant;
- (2) The 35-percent delivery requirement may be met for the current month or it may be met on the basis of

² This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

deliveries during the preceding 12-month period with the current month;

- (3) The plant is approved by a duly constituted health authority to handle milk for fluid consumption; and
- (4) The plant does not qualify as a pool plant under paragraph (a), (b), or (c) of this section or under the similar provisions of another Federal order applicable to a distributing plant or supply plant.
- (f) The percentage delivery requirement in paragraphs (b) and (d) of this section may be increased or decreased by up to 10 percentage points by the Director of the Dairy Division if the Director finds that such revision is necessary to obtain needed shipments or to prevent uneconomic shipments. Before making such a finding, the Director shall investigate the need for revision on either the Director's own initiative or at the request of interested persons. If the investigation shows that a revision might be appropriate, the Director shall issue a notice stating that revision is being considered and invite data, views, or arguments in favor of or in opposition to the proposed revision.
- 3. Section 1036.13 is amended by revising paragraph (e), the introductory text of paragraph (f), and paragraphs (f)(1)(ii) and (f)(2)(ii) to read as follows:

§1036.13 Producer milk.

- (e) During March through August and December, subject to the conditions of paragraph (g) of this section, the operator of a pool plant or a cooperative association may divert the milk of a producer without limit.
- (f) During September through February excluding December and subject to the conditions of paragraph (g) of this section:
 - (1) * * *
- (ii) The plant operator may divert an aggregate quantity of milk of producers not exceeding 40 percent of the producer milk received at or diverted from such pool plant during the month that is eligible to be diverted by the plant operator.

(20 * * *

(ii) The cooperative association may divert an aggregate quantity of milk not exceeding 40 percent of the producer milk that the cooperative association causes to be delivered to pool plants or diverted therefrom. United States Department of Agriculture, Agricultural Marketing Service

Marketing Agreement Regulating the Handling of Milk in the Eastern Ohio-Western Pennsylvania Marketing Area

The parties hereto, in order to effecutate the declared policy of the Act, and in accordance with the rules of practice and procedure effective thereunder (7 CFR Part 900), desire to enter into this marketing agreement and to hereby agree that the provisions referred to in paragraph I hereof as augmented by the provisions specified in paragraph II hereof, shall be and are the provisions of this marketing agreement as if set out in full herein.

I. The findings and determinations, order relative to handling, and the provisions of §§ 1036.1 to 1036.122, all inclusive, of the order regulating the handling of milk in the Eastern Ohio-Western Pennsylvania marketing area (7 CFR Part 1036) which is

annexed hereto; and

II. The following provisions: § 1036.123 Record of milk handled and authorization to correct typographical errors

authorization to correct typographical errors.
(a) Record of milk handled. The undersigned certifies that he handled during the month of May 1986, ______hundredweight of milk covered by this marketing agreement.

(b) Authorization to correct typographical errors. The undersigned hereby authorizes the Director, or Acting Director, Dairy Division, Agricultural Marketing Service, to correct any typographical errors which may have been made in this marketing agreement.

§ 1036.124 Effective date. This marketing agreement shall become effective upon the execution of a counterpart hereof the Secretary in accordance with section 900.14(a) of the aforesaid rules of practice and procedure.

In witness whereof, The contracting handlers, acting under the provisions of the Act, for the purposes and subject to the limitations herein contained and otherwise, have hereunto set their respective hands and

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FEDERAL ELECTION COMMISSION

11 CFR Part 110

[Notice 1986-4]

Contribution and Expenditure Limitations and Prohibitions

AGENCY: Federal Election Commission.
ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Commission requests comments on proposed revisions to its regulations at 11 CFR 110.3, 110.4, 110.5, and 110.6. These regulations implement provisions of the Federal Election Campaign Act of 1971 as amended, (the "Act" or "FECA"), 2 U.S.C. 431 et seq., which set forth limitations and prohibitions on contributions made to candidates and political committees with respect to Federal elections. The proposed revisions are intended to clarify the application of these sections and to address issues that have arisen since the current rules were promulgated in 1977. Please note that the draft rules that follow do not represent a final decision by the Commission on the amendment of §§ 110.3 through 110.6 of its regulations. The Commission also seeks comments on several issues that have arisen concerning these regulations that could be addressed in a revision of these rules. A public hearing has been scheduled to obtain further comment on the proposed amendments and the issues discussed in this notice. Further information is provided in the supplementary information which follows.

DATES: Comments must be received on or before August 29, 1986. The Commission will hold a hearing on September 17, 1986. Persons wishing to testify should so indicate in their written comments.

ADDRESSES: Comments should be made in writing and addressed to: Ms. Susan E. Propper, Assistant General Counsel, 999 E Street, NW., Washington, DC 20463.

FOR FURTHER INFORMATION CONTACT: Ms. Susan E. Propper, Assistant General Counsel, (202) 376–5690 or Toll Free (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Commission is considering revisions to §§ 110.3 through 110.6 of its regulations. The proposed revisions are intended to clarify the application of these sections and to address issues that have arisen since the current rules were promulgated in 1977. Please note, however, that the proposed rules that follow do not represent a final decision by the Commission on the text of any amendments to §§ 110.3 through 110.6.

The majority of the draft revisions would be made to § 110.3, governing contributions and transfers by affiliated committees and party committees, and to § 110.6, concerning earmarked contributions. The primary issues on which public comment is sought concern:

(1) The indicia of affiliation set forth in proposed § 110.3(a)(3) and (a)(4);

(2) Affiliation between a State committee and subordinate State committees of a political party under § 110.3(b)(3);

(3) Transfers of funds between candidate committees under § 110.3(c);

and

(4) Criteria for determining whether an individual or entity is acting as a conduit or intermediary under § 110.6, and criteria for establishing that the conduit exercised direction or control over the earmarked contribution.

A discussion of the proposed amendments to each section, as well as additional issues that could be addressed in a revision of these

sections, follows.

A. Section 110.3 Contribution limitations for affiliated committees and political party committees; Transfers.

Section 110.3 of the Commission's regulations sets forth the rules governing the application of the contribution limitations of 2 U.S.C. 441a(a) to affiliated committees and political party committees. It also contains provisions concerning transfers of funds between committees. Under the proposed rules, § 110.3 would be retitled "Contribution limitations for affiliated committees and political party committees; Transfers" to clarify that the section contains provisions relating to political party committees, as well as affiliated committees. As under the current regulations, paragraph (a) would implement the provisions against the proliferation of political committees (2 U.S.C. 441a(a)(5)) and paragraph (b) would set forth the rules governing the contribution limits of political party committees. Paragraph (c), as revised, would cross-reference the rules governing transfers and collecting agents at 11 CFR 102.6 and contain the rules governing transfers involving candidate committees currently found in § 110.3(a)(2)(iii), (a)(2)(iv), and (a)(2)(v).

1. Section 110.3(a) Contribution limitations for affiliated committees.

Section 110.3(a) of the proposed rules follows current § 110.3(a)(1) to govern contributions made by and to affiliated committees other than party committees. See 11 CFR 100.5(g) (Definition of affiliated committee.) Based upon current § 110.3(a)(1)(i), proposed § 110.3(a)(1) would implement the "antiproliferation" provisions of 2 U.S.C. 441a(a)(5). This section would, thus, state the general rule that, for the purposes of the contribution limitations set forth at 11 CFR 110.1 and 110.2, contributions by more than one political committee established, financed, maintained or controlled by any corporation, labor organization, or any other person or group of persons,

including any parent, subsidiary, branch, division, department or local unit, shall be considered to be made by

a single political committee.

The determination that committees are affiliated for the purposes of the contribution limits of § 441a(a) has several consequences. For example, under FECA, corporations and their political committees may solicit contributions only from certain classes of individuals. 2 U.S.C. 441b(b) (4) (A). Specifically, such corporations are restricted to soliciting contributions from their shareholders, executive and administrative personnel, and their families. 11 CFR 114.5(g). Once affiliation is established, however, corporations or their political committees may also solicit the shareholders, executive and administrative personnel of their "subsidiaries, branches, divisions and affiliates" and their families. 11 CFR 114.5(g) (1).

Several revisions have been proposed in this section to clarify which committees are subject to the "antiproliferation" provisions. For example, § 110.3(a) (1) would be revised under the proposed regulations to clarify that, in appropriate instances, the term "local unit" may include a franchisee, licensee, or State or regional association. See, e.g., Advisory Opinions ("AOs") 1979-

38, 1981-55, and 1982-46.

Proposed § 110.3(a) (2) would retain the list of examples of committees that share single contribution limit taken from the 1976 Conference Report (H.R. Rep. No. 1057, 94th Cong. 2d Sess. 58 (1976)) currently found in § 110.3(a) (1) (ii). Minor changes are proposed in this section to indicate that the committees established, financed, maintained, or controlled by the organizations listed are viewed as per se affiliated (see, e.g., AOs 1983-28 and 1983-46) are that other committees not specifically mentioned may also be considered affiliated and. therefore, subject to the "antiproliferation" rules.

The major revisions in draft paragraph (a), however, would be made to the indicia that may be used in determining whether affiliation exists between committees not considered per se affiliated currently set forth in § 110.3(a)(1)(iii). The major issues that have arisen under the present provisions of § 110.3(a)(1) have concerned the applications of these indicia. The proposed revisions are intended to further clarify when committees are affiliated because they are established, financed, maintained, or controlled by the same corporation, labor organization, or other person or group of persons, including a parent, subsidiary,

branch, division, department or local unit thereof. In this regard, draft § 110.3(a)(3)(i) would clarify that the Commission may examine a variety of relationships, including the relationship between sponsoring organizations between the committees themselves, or between one sponsoring organization and a committee established by another organization, to determine whether affiliation is present.

a. Indicia of Affiliation

Under the proposed rules, § 110.3(a)(3)(ii) would set forth factors the Commission could use to determine whether particular political committees are affiliated. This list of indicia of affiliation is not meant to be exhaustive, but only illustrative of the things that could be taken into account in making an affiliation determination. Paragraphs (a)(3)(ii) (A), (B), and (C) would be based upon the indicia contained in current § 110.3(a)(1)(iii) (A) through (C). Using these indicia to determine affiliation, the Commission could consider, whether one organization that sponsors a political committee possesses a controlling interest in another sponsoring organization, or the ability to direct the actions, or the authority to hire or remove the officers, employees, or members of another sponsoring organization or committee. The indicia set forth in paragraphs (a)(3)(ii) (B) and (C) may also be used to determine whether one political committee has the authority to govern the actions, officers or employees of another committee. Proposed § 110.3(a)(3)(iii) (D) through (F) would concern affiliation between organizations or committees that share common memberships, officers, employees, or funding. The final factor, in paragraph (a)(3)(ii) (G) permits consideration of whether the sponsoring organization or committee had a significant role in the formation of another committee in determining whether affiliation is present. The Commission requests comments on this proposed section and suggestions of other indicia that could be set forth in § 110.3.

In addition, the Commission requests comments on whether the indicia in proposed paragraph (a)(3) should be applied to determine if political committees established by candidates are affiliated with their principal campaign committees. The Commission is aware that increasing numbers of candidates are establishing political action committees that make contributions to Federal, state and local candidates on the founding candidates'

instruction. The Commission addressed this question in AO 1978-12, and noted that a committee established with the assistance of a congressman that intended to make contributions in consultation with him was not necessarily affiliated with his principal campaign committee if he had not given it written authorization. But, see, 11 CFR 110.1(h) and 110.6. The opinion did indicate, however, that it was limited to the specific facts of the request and did not "give blanket approval for the general proposal" described in the request. Thus, there may be circumstances under which a political action committee established by a candidate may be considered affiliated with his or her campaign committee for the purposes of the contribution limitations. See AOs 1986-6 and 1985-40. The Commission requests comments on whether § 110.3(a) should be revised to address this issue.

b. Conforming Amendments Regarding Indicia of Affiliation

The revisions to § 110.3 being proposed today could necessitate that conforming amendments be made to several other regulatory provisions concerning affiliated committees. For instance, the definition of "affiliated committee" at 11 CFR 100.5(g) contains the same list of indicia set forth in current § 110.3(a)(1)(iii) that would be revised under the draft rules. See 11 CFR 100.5(g)(2)(ii). It may be necessary fo revise this section to incorporate the indicia of affiliation proposed in draft § 110.3(a)(3).

In addition, the proposed rules may affect the reporting requirements for affiliated committees. Under 11 C.F.R. 102.2(b), a political committee is required to report the name of any connected organization or affiliated committee in its statement of organization. A cross-reference to \$ 110.3(a) could be included in \$ 102.2(b) to provide guidance as to the committees that would be considered affiliated and, thus, subject to this

reporting requirement.

Finally, the proposed revision of the indicia of affiliation could affect a determination regarding the solicitation rights of various incorporated entities. Pursuant to § 114.5(g)(1), a corporation may solicit the executive and administrative personnel of its "subsidiaries, branches, divisions and affiliates" and their families for contributions to a separate segregated fund. Incorporated membership organizations, cooperatives and corporations without capital stock may similarly solicit the members, as well as the executive and administrative

personnel, and their families of their affiliates. 11 CFR 114.7. In particular, a federation of trade associations may solicit the members of the federation's regional, state or local affiliates pursuant to 11 CFR 114.8(g) if all the political committees established, financed, maintained or controlled by the federation and its affiliates are considered one political committee for the purposes of the contribution limitations.

The Commission has used the indicia set forth in current § 110.3(a)(1)(iii) to determine whether a particular organization was affiliated with a corporation and its status within the corporate structure for solicitation purposes. See, e.g., AOs 1985-31, 1985-27, 1984-36, 1983-49, 1983-46, 1981-55, and 1980-18. This approach is most evident in the advisory opinions the Commission has issued according "affiliate" status under 11 CFR 114.5(g) to corporations and their franchisees or licensees. See AOs 1977-70, 1978-39, 1978-61, and 1978-38. In these opinions, the Commission concluded that various corporations and their franchisees or licensees were affiliated due to the nature and extent of the licensee's obligations to the corporation and the corporation's continuing control and direction over the business policies, practices and procedures of the licensees. The Commission noted that, as a result of their affiliation, all political committees established by the particular corporation and its affiliated franchisees were considered a single political committee for the purposes of the contribution limitations and that the organizations were affiliated for solicitation purposes under § 114.5(g)(1). Compare AO 1985-7 (Corporation and its wholesale distributorships were not affiliated for the purposes of § 114.5(g)(1) because the degree of influence exercised by the corporation over wholesalers was insufficient to meet the standards set forth in the opinions concerning corporate franchisees and licensees.)

The Commission has noted that, although the term "affiliate" in § 114.5(g) is not defined, it has applied the indicia of affiliation in § 110.3(a)(1)(iii) to determine whether particular corporations were affiliated for solicitation purposes under § 114.5(g). See AOs 1985–31 and 1983–48. In view of this, sections 114.5(g), 114.7, and 114.8(g) could be revised to crossreference the expanded set of indicia of affiliation in draft paragraph (a)(3) that could be used to make such determinations under the proposed rules. However, the question arises of whether the proposed rules

make it clear that the factors listed concerning affiliation between political committees may in addition be used to determine affiliate status under Part 114 of the Commission's regulations. It may be that a separate regulatory provision is necessary to address such determinations. The Commission seeks comments on this issue and the proposed conforming amendments discussed in this section.

2. Section 110.3(b) Contribution limitations for party committees.

As under the current regulations, proposed § 110.3(b) would implement 2 U.S.C. 441a(a)(5)(B) to clarify that the "anti-proliferation" provisions do not apply to certain political party committees. Thus, § 110.3(b)(1) provides that all contributions made by the national committee of a political party and its political committees and those made by the State committees of the same political party are considered to be made by separate political committees.

The proposed regulations would revise § 110.3(b)(2) in two respects to clarify the application of the contribution limitations with respect to political party committees on the national and state levels. First, draft § 110.3(b)(2)(i) would delineate the contribution limitations for the national committee and the House and Senate campaign committees of the same political party currently set forth in paragraphs (b)(2)(i) and (b)(4). As revised, this paragraph would clarify that a party's Senate campaign committee and its national committee share the \$17,500 limitation on contributions to senatorial candidates (see, 11 CFR 110.2(c) and 2 U.S.C. 441a(h)), but have separate limits for contributions to other candidates and committees.

The second set of proposed revisions would govern contributions by State party committees. Currently. § 110.3(b)(2)(ii) establishes a presumption that contributions by political committees established, financed, maintained, or controlled by the State committee and any subordinate committee within the state are made by one political committee. It also provides that this presumption will not apply if political committees established by either party unit neither receive funds from nor coordinate contributions with political committees of the other party unit. However, the current regulations do not describe all the types of interactions that could be relevant in determining whether party committees within a state have received funds or coordinated contributions with

each other. See AO 1978–9 and AOR 1984–9. Concerns have been raised about the application of the presumption set forth in current § 110.3(b)(2)(ii), as well as the Commission's decision in AO 1978–9. See, e.g., dissent to AO 1978–9.

Section 110.3(b)(3) has been proposed in an attempt to clarify when a subordinate State committee wil be considered to have a separate contribution limit from that of the State committee. The draft provisions would continue to provide in paragraph (b)(3) that contributions made by State committees and subordinate State committees shall be considered to be made by one political committee for the purposes of the contribution limitations. A State committee or subordinate State committee wishing to have a separate contribution limit would be required to demonstrate its independence under the criteria stated in proposed paragraphs (b)(3)(i) through (iv). The Commission requests comments on draft § 110.3(b)(3) and proposals for other factors that could be considered in determining whether a subordinate State committee and the State committee are separate political committees for the purposes of the contribution limitations.

3. Section 110.3(c): Transfers. The final area in which the Commission is proposing revisions to § 110.3 concerns the provisions on transfers of funds currently contained in paragraphs (a)(2) and (c). Under the proposed rules, § 110.3(c)(1) would provide a cross-reference to the Commission's regulations governing transfers and collecting agents at 11 CFR 102.6. Draft § 110.3(c)(2) would follow current § 110.3(a)(2)(i) to state that the rules set forth in this section do not limit the transfer of the proceeds of a joint fundraising activity. The remaining provisions of § 110.3(c) would retain the special rules regarding transfers involving candidate committees currently found in paragraphs (a)(2)(iii) through (a)(2)(v). Thus, draft paragraphs (c)(3) and (c)(4) follow current § 110.3(a)(2)(iii) and § 110.3(a)(2)(iv) to permit transfers between a candidate's primary and general election campaigns or a candidate's previous and currently registered campaign committees. These sections have not been revised in this draft of the proposed rules.

However, the Commission is considering whether to revise these rules to address transfers of funds from state campaigns to federal campaigns. While the current regulations do not specifically refer to such transfers, the Commission has addressed issues arising from such transfers in several

advisory opinions. See, e.g., AOs 1982-52, 1983-34, 1984-46, and 1985-2. The Commission has permitted candidates to transfer funds from a previous state campaign to a current Federal campaign committee, viewing them as transfers between affiliated committees under § 110.3(a)(2)(iv). Since transfers count toward the thresholds for political committee status under the Act, the Commission determined that the state committees would be required to register and report on a one time basis if the transfer reached the appropriate dollar threshold. Moreover, the state committees have only been permitted to transfer funds to the extent the funds were not received from prohibited sources and did not exceed the contribution limits of persons that had already contributed to the federal committee. To determine this amount, the Commission required that the funds to be transferred by reviewed on a "last received, first transferred" basis. Any portion contributed from sources, such as corporations or labor organizations, prohibited from making contributions in connection with federal elections were to be excluded from the funds to be transferred. Contributions of any person included in the amount transferred had to be aggregated with those to the federal committee. The Commission requests comments on whether § 110.3 should be amended to add provisions concerning transfers from a state campaign to a federal campaign along these lines.

Proposed §110.3(c)(5) follows present § 110.3(a)(2)(v) governing transfers between the principal campaign committees fo a candidate seeking nomination or election to more than one Federal office. While the Commission has not proposed revisions to this section in this notice, it is considering amending this provision in three respects. One area in which revisions could be made would be to clarify when a candidate would be considered to be seeking nomination or election to more than one Federal office. For example, the Commission determined in AO 1982-22 that when a candidate changes the congressional district he or she is running in, it is not considered running in separate elections for the purposes of the contribution limitations. Compare AO 1978-19 (Two Senate seats spanning different terms considered different offices for the purposes of § 110.3(a)(2)(v).)

In addition, the Commission is considering whether to revise the definition of the term "not actively seeking" for the purposes of this section. The current rules note two instances under which a candidate will not be

considered to be actively seeking nomination or election to more than one office. Specifically, the candidate's principal campaign committee must have filed a termination report with the Commission or notified the Commission that it will no longer make any expenditures except to retire outstanding debts. The Commission is considering amending this section to include other circumstances under which a candidate would be viewed as "not actively seeking" could be revised, for example, to include candidates prohibited from running for more than one office by operation of State law. See AO 1986-12.

The final area in which the Commission is considering revisions to this section would address issues arising when a candidate abandons a campaign for a second Federal office and reactivates a previous campaign for another Federal office. This issue arose in AO 1984-38. In that opinion, the Commission noted that the procedure set forth at § 110.3(a)(2)(v)(B) regarding counting contributions for purposes of the contribution limits does not contemplate reactivation of a prior campaign. The Commission determined, however, that if a contribution made to the campaign for the first office is transferred to the campaign for the second office, it becomes applicable to the contribution limits for the second office. Yet, the contribution should still be attributed to the contribution limits for the first office, as well, unless the donor redesignates it in writing for the second office. If a contribution is redesignated, it must be aggregated with other contributions by that donor to the second campaign.

The Commission requests comments on whether proposed § 110.3(c)(5) should be revised along the aforementioned lines and suggestions on how this should be done.

B. Section 110.4 Prohibited Contributions.

This section sets forth provisions concerning various contributions that are prohibited under the Act. The Commission is not proposing any revisions to the text of the regulations in this notice. Therefore, as under the current rules, § 110.4(a) implements 2 U.S.C. 441e to prohibit contributions by foreign nationals in connection with elections for Federal, State or local offices and to prohibit soliciting or accepting such contributions. It also provides that the terms "foreign national" means a foreign principal as defined at 22 U.S.C. 611(b) or an individual who is not a United States citizen and has not been admitted for

permanent residence as defined in 8

U.S.C. 1101(a)(20).

Paragraph (b) prohibits contributions made in the name of another and knowing acceptance of such contributions. See 2 U.S.C. 441f.

Examples of contributions considered to be made in the name of another are contained in paragraph (b)(2).

Section 110.4(c) governs contributions of currency. Implementing 2 U.S.C. 441g, paragraph (c) prohibits cash contributions in excess of \$100 with respect to any campaign for federal office and requires that any part of a cash contribution exceeding \$100 be returned to the contributor. Section 110.4(c)(3) concerns treatment of anonymous cash contributions in excess of \$50 and makes it clear that a committee must dispose of the portion that exceeds \$50.

The Commission requests comments on the provisions of § 110.4.

C. Section 110.5 Annual Contribution

Limitation.

Section 110.5 of the Commission's regulations sets forth rules governing the \$25,000 limitation on contributions made by individuals in a calendar year. See 2 U.S.C. 441a(a)(3). No major substantive revisions would be made to this section under the proposed rules. However, proposed § 110.5(a) would add a new paragraph to the regulations to clarify that this section only applies to contributions by individuals permitted to make contributions under the Act. This section would not apply, for example, to foreign nationals or federal contractors.

The other provisions of the draft rules follow the current regulations with minor clarifying revisions. Thus, proposed § 110.5(b) would state the \$25,000 annual limitation on contributions by individuals currently found at § 110.5(a). Paragraph (c) would follow present § 110.5(b) with certain amendments to clarify when a contribution made in a nonelection year will be considered to be made in an election year for the purposes of the annual contribution limitation. In this regard, a proposed definition of the term "nonelection year" has been included in this draft to avoid the confusion that has resulted from the repetition of the phrase "in a year other than the calendar year in which an election is held" throughout this section.

Proposed paragraph (d) would contain the provisions of present § 110.5(c) to explain that the annual limitation applies to contributions made to persons making independent expenditures, including political committees. Finally, paragraph (e) would follow current § 110.5(d) to provide that the \$25,000

annual limitation applies to contributions made to delegates and delegate committees under 11 CFR 110.14.

The Commission requests comments on the text of the proposed revisions to § 110.5 and recommendations of other amendments that would further clarify the application of the annual contribution limitation under section 441a(a)(3).

D. Section 110.6 Earmarked Contributions.

11 CFR 110.6 implements 2 U.S.C.
441a(a)(8). Under that provision of the
Act, contributions made by a person,
either directly or indirectly, on behalf of
a particular candidate, including
contributions earmarked or otherwise
directed through an intermediary or
conduit to the candidate, are
contributions from the person to the
candidate. Section 441a(a)(8) requires
the intermediary or conduit to report the
original source and the intended
recipient of the contribution to the
Commission and to the intended
recipient.

1. Section 110.6(a) General.

Section 110.6(a) restates the statutory requirement that all contributions by a person which are in any way earmarked or otherwise directed through a conduit or intermediary to a particular candidate shall be treated as contributions by the person to the candidate. The attached proposed rules would not substantively amend this provision.

2. Section 110.6(b) Definition.

The definition of "earmarked" would not be substantively revised under the proposed rules being published today.

The Commission is considering whether paragraph 110.6(b) should be expanded to include a definition of the terms "conduit or intermediary" in order to clarify the scope of the earmarking regulations. There appears to be some confusion as to who is subject to the requirements of § 110.6 because neither the Act nor current § 110.6 defines these terms. The Commission notes that conduits and intermediaries need not be political committees and that the reporting obligations for conduits and intermediaries under 2 U.S.C. 441a(a)(8) are separate and distinct from the reporting obligations for political committees under 2 U.S.C. 434. In this context, the following issues have been raised regarding the scope of § 110.6:

a. Should the Commission continue to permit separate segregated funds to serve as conduits for earmarked contributions?

b. Does § 110.6 apply to contributions earmarked to political committees that

are not the authorized committees of candidates?

c. Should § 110.6 be amended to include a list of factors to be applied in determining whether an individual or entity is acting as a conduit or intermediary?

a. Separate Segregated Funds as Conduits

Concerns have been raised as to the permissibility of earmarking contributions through separate segregated funds ("SSFs") to candidates and their authorized committees. Although present § 110.6 is silent on this point, three advisory opinions have addressed the legitimacy of SSFs acting as conduits for earmarked contributions. See AOs 1986–4, 1981–21 and re: AOR 1976–92.

Recently, in AO 1986-4 a corporation described a proposed political contribution program and asked whether it would be required to register and report as a SSF or as a conduit. The Commission concluded that the proposed activity would violate 2 U.S.C. 441b unless the corporation formed a SSF for that purpose. Moreover, the Commission stated that a corporation's SSF could act as a conduit for earmarked contributions. The issue addressed in AO 1981-21 concerned the transfer of funds from a corporation's state political action committee to the corporation's federal political action committee for the purpose of making contributions to particular candidates. In approving the transfer, the Commission observed that the federal political action committee was serving as a conduit for contributions which the original contributor earmarked for the particular candidates at the time they were transmitted to the state political action committee. Consequently, the Commission stated that the SSF was required to comply with the reporting obligations of § 110.6. In AOR 1976-92 the requestor described its political fundraising activities and asked whether it should be considered to be a SSF. In response, the Commission indicated that it would be a SSF and that it would be subject to the § 110.6 reporting requirements because it would be receiving contributions designated for particular candidates.

The Commission notes that the House Report accompanying the 1974 amendments to the Act states that the earmarking provisions "are not intended to apply to contributions from separate segregated funds maintained by corporations or labor organizations, because donors to such funds must relinquish control of their donation to

the corporation or labor organization and such donors may not earmark or direct such donations to any specific candidate or political committee." H.R. Rep. No. 1239, 93d Cong., 2d Sess. 15 (1974). The Conference Report repeats the language in the House Report and states that the Conference substitute is the same as the House amendment with certain exceptions not relevant here. H.R. Rep. No. 1438, 93d Cong., 2d Sess. 51, 52 (1974). Thus, an argument can be made that the language in the House Report and the Conference Report prohibits the earmarking of contributions through SSFs. This prohibition could be justified on the grounds that the corporation or labor organization has the right to control contributions by the SSF. See 11 CFR 114.5(d). In addition, the prohibition would prevent the corporation or labor organization from making indirect contributions by paying the expenses incurred in soliciting contributions earmarked for particular candidates. Comments are requested as to whether § 110.6 should explicitly prohibit earmarking through SSFs. The alternative would be to permit SSFs to receive and forward earmarked contributions provided that such contributions are limited to the amount that the original contributor may lawfully contribute directly to the candidate. Another alternative would be to permit SSFs to receive and forward earmarked contributions but to specifically prohibit the corporation or labor organization from exercising any direction or control over the choice of the recipient candidate either before or after the contribution is made.

b. Contributions Earmarked to **Unauthorized Committees**

A question has arisen as to whether § 110.6 applies to a contribution earmarked to an unauthorized committee, such as a political action committee. 2 U.S.C. 441a(a)(8) and present § 110.6 do not address this situation because the contribution is not earmarked to a particular candidate. In AOs 1983-18 and 1981-57, the Commission stated that conduits are not barred from forwarding earmarked contributions to political committees that are not authorized committees of candidates, and if they choose to do so, the forwarding requirements of 11 CFR 102.8 apply. Under the proposed revisions to § 110.6(b), conduits would not be required to report contributions earmarked to unauthorized committees, but would continue to be subject to the forwarding and accounting provisions of 11 CFR 102.8 once they decide to accept earmarked contributions. The

Commission is also considering whether the revised rules should state that conduits are free to reject and return earmarked contributions. Comments are requested on these points.

c. Criteria for distinguishing conduits

Questions have been raised as to whether certain fundraising activities will cause individuals and entities to be considered conduits or intermediaries subject to the provisions of § 110.6. The Commission is considering providing additional guidance in this area, and requests comments on including in § 110.6 a list of criteria to be considered in making these determinations. For example, the rule could provide that the following circumstances demonstrate that an individual or entity which forwards earmarked contributions is a conduit:

(1) The individual or entity has not been retained by the candidate's committee for the purpose of fundraising and is not reimbursed for expenses incurred in soliciting contributions;

(2) In the case of an individual, the candidate has not expressly authorized the individual to engage in fundraising and the individual does not occupy a significant position within the candidate's campaign organization; or

(3) The entity forwarding contributions to the candidate is a political committee not affiliated with the candidate's campaign organization.

The Commission requests public comment as to what other criteria would be useful or dispositive in making conduit determinations. To be workable, the criteria should not be so broad as to include as conduits full-time volunteers working in the candidate's campaign organization.

3. Section 110.6(c) Reporting of earmarked contributions.

The Commission notes that often contributions must be reported by several entities under different provisions of the Act. The principal reporting provision is 2 U.S.C. 434, which requires political committees, including committees authorized by candidates, to report their receipts and disbursements to the Commission. 2 U.S.C. 441a(a)(8) requires conduits and intermediaries to report the source and intended recipient of earmarked contributions to the Commission and to the intended recipient. 2 U.S.C. 432(b) is in some respects a reporting provision as it requires persons receiving contributions for authorized and unauthorized political committees to forward certain information together with the contribution to the committee's treasurer, but not to the Commission. Through its regulations, specifically 11

CFR Part 104 and §§ 102.8 and 110.6, the Commission has attempted to set forth a reporting and recordkeeping system which takes into account the overlapping requirements of these statutory provisions.

The proposed rules would revise and reorganize the provisions in § 110.6(c) regarding the reporting of earmarked contributions. Paragraph 110.6(c)(1), as revised, would consolidate the conduit reporting provisions in current paragraphs (c)(1), (c)(2), (c)(4), and (c)(5). Proposed paragraph 110.6(c)(2) would set forth reporting requirements for recipient candidates and their authorized committees, and would be based on present paragraph (c)(3).

Proposed paragraph (c)(1) would generally follow the provisions of current paragraph (c)(1). Under present (c)(1), the conduit's report of earmarked contributions shall be included in the conduit's next due report to the Commission. The proposed rules would clarify that this information should be included in the conduit's report for the reporting period in which they were received. Proposed § 110.6(c)(1) would not alter the current requirement that conduits not subject to the reporting requirements of 11 CFR Part 104 must report earmarked contributions to the Commission by letter. Current § 110.6(c)(1) has caused some confusion as it does not provide a due date for the letter. Therefore, the Commission may wish to establish a due date and is considering several alternatives. For example, the conduit could be required to file the letter within 30 days after forwarding the earmarked contribution. Another possibility is to require filing of the letter within the same time-frame used by reporting entities. See 11 CFR 104.5. Under the proposed revisions, (c)(1) would provide that the conduit may use a memo entry to report contributions passed on by means of the contributor's check. Under the present regulations, conduits must report these contributions on separate schedules.

Proposed paragraph (c)(1) would also incorporate (c)(2) of the current regulations, which provides that the information pertaining to earmarked contributions shall be supplied to the candidate at the same time that the contribution is passed on to the intended recipient. For clarity, this paragraph would cross-reference the ten-day forwarding requirement of 11

In addition, proposed paragraph (c)(1) would follow present paragraph (c)(4) regarding the information which the conduit must report. Under that provision, the conduit must report the

name and address of the contributor, the amount of the contribution, the date the conduit received it, the intended recipient's name, the date the contribution was forwarded and whether it was forwarded in cash, by the contributor's check or by the conduit's check. For contributions exceeding \$200, the report must also include the contributor's occupation and the name of his or her employer.

Finally, proposed paragraph (c)(1) would incorporate present paragraph (c)(5). That paragraph creates an exception to the reporting requirements for "occasional, isolated, or incidental physical transfers of checks or other written instruments payable to a candidate or his or her authorized committee" aggregating \$1,000 or less per candidate per year. This provision was enacted when the Commission had authority to grant waivers to the reporting obligations. As the Commission no longer has waiver authority, comments are requested on whether to delete the exception.

Proposed § 110.6(c)(2) would require candidates and their authorized committees to report the receipt of earmarked contributions. Under the present rules, all intended recipients must report earmarked contributions. The Commission is considering restricting the reporting obligation to intended recipients that are candidates or authorized committees because 2 U.S.C. 441a(a)(8) refers to contributions earmarked to a particular candidate, but does not mention contributions earmarked to other recipients, such as political action committees.

Proposed paragraph (c)(2) would amend the reporting requirements for candidates and authorized committees in several other respects. The revisions would clarify that the § 110.6 reporting obligations only apply if the candidate or committee receives one or more earmarked contributions from a conduit which total over \$200 in a calendar year. The recipient candidate or committee would be required to itemize the identification of the conduit, the total amount received from the conduit and the date of receipt. If a single contribution exceeds \$200, the candidate or committee would also be required to itemize the identification of the contributor, the amount, and the date of receipt. For earmarked contributions of \$200 or less, the reporting requirements in 11 CFR Part 104 would apply. Comments are requested on these proposed amendments.

4. Section 110.6(d) Direction and control over earmarked contributions.

The Commission is considering several revisions to § 110.6(d) that

would address the problems that have arisen with regard to this paragraph. 11 CFR 110.6(d) currently requires contributions over which the conduit exercises direction or control to be considered contributions by both the contributor and the conduit and to be reported as such. This rule is based on the House Report accompanying the 1974 amendments to the Act. It states that "if a person exercises any direct or indirect control over the making of a contribution, then such contribution shall count toward the limitation imposed with respect to such person under [current 2 U.S.C. 441a], but it will not count toward such a person's contribution limitation when it is demonstrated that such person exercised no direct or indirect control over the making of the contribution involved." H.R. Rep. No. 1239, 93d Cong., 2d Sess. 16 (1974). The Conference Report repeats this language and states that the Conference substitute is the same as the House amendment with certain exceptions not relevant here. H.R. Rep. No. 1438, 93d Cong., 2d Sess. 51, 52 (1974). Although the draft rules which follow retain the phrase "direction or control", the Commission is considering whether the phrase "direct or indirect control" should be used instead, since it more closely conforms to the language in the committees' reports. This change would not alter the circumstances in which the rule would apply. The Commission notes that 2 U.S.C. 441a(a)(8) refers to contributions made "directly or indirectly" on behalf of a particular candidate.

Currently, § 110.6(d) does not provide criteria for determining whether a conduit exercised "direction and control" or "direct or indirect control" over an earmarked contribution. In AO 1980-46 the Commission distinguished a "suggestion" to make a contribution from actual direction and control over the contribution. The Commission considered whether the conduit controlled the amount and timing of the contribution and whether the conduit selected the intended recipient. See also MUR 1028, AO 1986-4 and re: AOR 1976-92. Comments are requested as to whether these should be included in the revised rules as criteria for establishing direction and control. The Commission also seeks suggestions of other criteria that would enable conduits to ascertain whether their activities cause them to cross the direction and control threshold.

Finally, proposed § 110.6(d) is intended to clarify the reporting of contributions over which the conduit exercises control. The conduit's reports

to the Commission and to the recipient should indicate that the contribution is made by both the original contributor and the conduit, and that the entire amount is attributed to each of them. The recipient candidate or authorized committee should also report the dual attribution of the contribution.

The Commission welcomes comments on the foregoing proposed amendments to 11 CFR 110.3 through 110.6 and the issues raised in this Notice.

Authority: 2 U.S.C. 432(c)(2), 438(a)(8), 441a, 441e, 441f, 441g.

List of Subjects in 11 CFR Part 110

Campaign funds, Elections, Political candidates, Political committees and parties, Reporting requirements.

Certification of No Effect Pursuant to 5 U.S.C. 605(b) [Regulatory Flexibility Act]

The attached proposed rules, if promulgated, will not have a significant economic impact on a substantial number of small entities. The basis for this certification is that the primary purpose of the proposed revisions is to clarify the Commission's rules regarding affiliation, transfers, prohibited contributions, limits on contributions, and earmarking. This does not impose a significant economic burden because any entities affected are already required to comply with the Act's requirements in these areas.

PART 110-[AMENDED]

It is proposed to amend 11 CFR Part 110 as follows:

1. By revising the authority citation for Part 110 to read as follows and removing the authority citations following all the sections in Part 110:

Authority: 2. U.S.C. 432(c)(2), 437d(a)(8), 438(a)(8), 441a, 441d, 441e, 441f, 441g, 441h, and 441i.

- 2. By revising 11 CFR 110.3 to read as follows:
- § 110.3 Contribution limitations for affiliated committees and political party committees; Transfers (2 U.S.C. 441a(a)(5), 441a(a)(4)).
- (a) Contribution limitations for affiliated committees. (1) For the purposes of the contribution limitations of 11 CFR 110.1 and 110.2, all contributions made to or by more than one affiliated committee, regardless of whether they are political committees under 11 CFR 100.5, shall be considered to be made to or by a single political committee. See 11 CFR 100.5(g). Application of this paragraph means that all contributions made to or by the following committees shall be considered to be made to or by a single political committee—

- (i) Authorized committees of the same candidate; or
- (ii) Committees (including a separate segregated fund, see 11 CFR Part 114) established, financed, maintained or controlled by the same corporation, labor organization, person or group of persons, including any parent, subsidiary, branch, division, department or local unit thereof. For the purposes of this section, "local unit" may include, in appropriate cases, a franchisee, licensee, or State or regional association.
- (2) Affiliated committees sharing a single contribution limitation under paragraph (a)(1)(ii) of this section include all of the political committees established, financed, maintained or controlled by—

(i) A single corporation and/or its subsidiaries;

(ii) A single national or international union and/or its local unions or other subordinate organizations;

(iii) An organization of national or international unions and/or all its State

and local central bodies;

- (iv) A membership organization, (other than political party committees, see paragraph (b) of this section) including trade or professional associations, see 11 CFR 114.8(a), and/or related State and local entities of that organization or group; or
 - (v) The same group of persons.
- (3) (i) The Commission may examine the relationship between organizations that sponsor political committees, between the committees themselves, or between one sponsoring organization and a committee established by another organization to determine whether political committees are affiliated.

(ii) For political committees not described in paragraphs (a)(2)(i)-(iv) of this section, factors the Commission may consider in determining whether political committees are affiliated include, but are not limited to:

(A) Whether a sponsoring organization owns a controlling interest in the voting stock or securities of the sponsoring organization of another committee;

(B) Whether a sponsoring organization or committee has the authority or ability to direct or participate in the governance of another sponsoring organization or committee through provisions of constitutions, bylaws, contracts, or other rules, practices or procedures:

(C) Whether a sponsoring organization or committee has the authority or ability to hire, appoint, or demote the officers, employees, or members of another sponsoring organization or committee;

(D) Whether a sponsoring organization or committee has a common or overlapping membership with another sponsoring organization or committee;

(E) Whether a sponsoring organization or committee has common or overlapping officers or employees with another sponsoring organization or committee:

(F) Whether a sponsoring organization or committee provides funds in a significant amount or on an ongoing basis to another sponsoring organization or committee, such as through direct or indirect payments for administrative, fundraising, or other costs, but not including the transfer to a committee of its allocated share of proceeds jointly raised pursuant to 11 CFR 102.6(b)(1)(iv) or 102.17;

(G) Whether a sponsoring organization or a committee had a significant role in the formation of another sponsoring organization or

committee.

(b) Contribution limitations for political party committees. (1) For the purposes of the contribution limitations of 11 CFR 110.1 and 110.2, all contributions made by or to the following committees shall be considered to be made by or to separate political committees—

(i) The national committee of a political party and any political committees established, financed, maintained, or controlled by the same national committee and

national committee and

(ii) The State committee of the same political party.

(2) Application of paragraph (b)(1)(i)

of this section means that-

(i) The House campaign committee and the national committee of a political party shall have separate limitations on contributions under 11 CFR 110.1 and 110.2.

(ii) The Senate campaign committee and the national committee of a political party shall have separate limitations on contributions, except that contributions to a senatorial candidate made by the Senate campaign committee and the national committee of a political party are subject to a single contribution limitation under 11 CFR 110.2(c).

(3) Application of paragraph (b)(1)(ii) of this section means that all contributions made to or by the political committees established, financed, maintained or controlled by a State party committee and by subordinate State committees shall be considered to be made to or by one political committee, except that any State party committee or subordinate State committee able to demonstrate its independence under the following

criteria shall have a separate contribution limitation:

 (i) Neither committee has a role in the formation of the other committee, such as through the development of its constitution or bylaws;

(ii) The committees conduct their activities, such as the election of officers, independently;

(iii) Neither committee makes contributions or expenditures in cooperation, consultation or concert with or at the request or suggestion of the other committee; and

(iv) The committees neither receive funds from nor donate funds to the other, except proceeds from a joint fundraising activity conducted pursuant to 11 CFR 102.17 provided that—

(A) Funds advanced by each committee for fundraising costs are in proportion to the agreed upon allocation formula pursuant to 11 CFR 102.17(b)(3)(i); and

(B) Expenses are allocated and net proceeds distributed pursuant to 11 CFR

102.17(c)(7)(i).

(c) Transfers. The contribution limitations of 11 CFR 110.1 and 110.2 shall not limit—

(1) Transfers between affiliated committees or party committees of the same political party or by collecting agents to a separate segregated fund made pursuant to 11 CFR 102.6;

(2) Transfers of joint fundraising proceeds between organizations or committees participating in the joint fundraising activity provided that no participating committee or organization governed by 11 CFR 102.17 received more than its allocated share of the funds raised;

(3) Transfers between the primary campaign and general election campaign of a candidate of funds unused for the

primary;

(4) Transfers between a candidate's previous campaign committee and his or her currently registered principal campaign committee or other authorized committee, as long as none of the funds transferred contain contributions which would be in violation of the Act; or

(5) Transfers between the principal campaign committees of a candidate seeking nomination or election to more than one Federal office, as long as the

following conditions are met:

(i) The transfer is made when the candidate is not actively seeking nomination or election to more than one office. For purposes of this paragraph, "not actively seeking" means a principal campaign committee has filed a termination report with the Commission, or has notified the Commission that the candidate and his authorized

committees will make no further expenditures, except in connection with the retirement of debts outstanding at the time of the notification;

(ii) The limitations on contributions by persons are not exceeded by the transfer. To assure this, the contributions making up the funds transferred shall be reviewed, beginning with the last received and working back until the amount transferred is reached. A person's contribution or any portion thereof, shall be excluded if, when added to contributions already made to the transferee principal campaign committee, the transferred contribution causes the contributor to exceed his or her limitation; and

(iii) The candidate has not received funds under 26 U.S.C. 9006 or 9037.

3. By revising 11 CFR 110.4 to read as

§ 110.4 Prohibited contributions (2 U.S.C. 441e, 441f, 441g, 432(c)(2)).

(a) Contributions by foreign nationals. (1) A foreign national shall not directly or through any other person make a contribution, or expressly or impliedly promise to make a contribution, in connection with a convention, caucus, primary, general, special, or runoff election in connection with any local, State or Federal public office.

(2) No person shall solicit, accept, or receive a contribution as set out above

from a foreign national.

(3) For purposes of this section. "foreign national" means-

(i) A foreign principal, as defined in 22

U.S.C. 611(b); or

(ii) An individual who is not a citizen of the United States and who is not lawfully admitted for permanent residence, as defined in 8 U.S.C. 1101(a)(20);

(iii) Except that "foreign national" shall not include any individual who is a citizen of the United States.

(b) Contributions in the name of another. (1) No person shall-

(i) Make a contribution in the name of

(ii) Knowingly permit his or her name to be used to effect that contribution; or

(iii) Knowingly accept a contribution made by one person in the name of another.

(2) Examples of "contributions in the name of another" include-

(i) Giving money or anything of value, all or part of which was provided to the contributor by another person (the true contributor) without disclosing the source of money or the thing of value to the recipient candidate or committee at the time the contribution is made, see § 110.6; or

(ii) Making a contribution of money or anything of value and attributing as the source of the money or the thing of value another person when in fact the contributor is the source.

(c) Cash contributions. (1) With respect to any campaign for nomination for election or election to Federal office, no person shall make contributions to a candidate or political committee of currency of the United States, or of any foreign country, which in the aggregate exceed \$100.

(2) A candidate or committee receiving a cash contribution in excess of \$100 shall promptly return the amount

over \$100 to the contributor.

(3) A candidate or committee receiving an anonymous cash contribution in excess of \$50 shall promptly dispose of the amount over \$50. The amount over \$50 may be used for any lawful purpose unrelated to any Federal election, campaign, or candidate.

4. By revising 11 CFR 110.5 to read as

§ 110.5 Annual contribution limitation (2 U.S.C. 441a(a)(3)).

(a) Scope. This section applies to all contributions made by any individual, except individuals prohibited from making contributions under 11 CFR 110.4 and 11 CFR Part 115.

(b) Annual Limitation. No individual shall make contributions to any candidate or political committee aggregating more than \$25,000 in any

calendar year.

(c) Contributions made in a nonelection year. (1) For the purposes of this section, "nonelection year" means a year other than the calendar year in which a particular election is held.

(2) For purposes of this section, any contribution to a candidate or his or her authorized committee with respect to a particular election made in a nonelection year shall be considered to be made during the calendar year in which such election is held.

(3) For purposes of this section, any contribution to an unauthorized committee which is made in a nonelection year shall not be considered to be made during the calendar year in which an election is held unless:

(i) The political committee is a single candidate committee which has supported or anticipates supporting the

candidate: or

(ii) The contribution is earmarked by the contributor for a particular candidate with respect to a particular election.

(d) Independent expenditures. The annual limitation on contributions in this section applies to contributions

made to persons, including political committees, making independent expenditures under 11 CFR Part 109.

(e) Contributions to delegates and delegate committees. The annual limitation on contributions in this section applies to contributions to delegates and delegate committees under 11 CFR 110.14.

5. By revising 11 CFR 110.6 to read as follows:

§ 110.6 Earmarked contributions (2 U.S.C. 441a(a)(8)).

(a) General. All contributions by a person made on behalf of or to a candidate, including contributions which are in any way earmarked or otherwise directed to the candidate through an intermediary or conduit, are contributions from the person to the candidate.

(b) Definition. For purposes of this section, "earmarked" means a designation, instruction, or encumbrance, whether direct or indirect, express or implied, oral or written, which results in all or any part of a contribution or expenditure being made to, or expended on behalf of, a clearly identified candidate or a candidate's authorized committee.

(c) Reporting of earmarked contributions.—(1) Reports by conduits and intermediaries.

(i) The intermediary or conduit of the earmarked contribution shall report the original source and the recipient candidate or authorized committee to the Commission, the Clerk of the House of Representatives, or the Secretary of the Senate, as appropriate (see 11 CFR Part 105), and to the recipient candidate or authorized committee.

(ii) The report to the Commission, Clerk or Secretary shall be included in the conduit's or intermediary's report for the reporting period in which the earmarked contribution was received, or, if the conduit or intermediary is not required to report under 11 CFR Part 104. by letter to the Commission.

(iii) The report to the recipient candidate or authorized committee shall be made when the earmarked contribution is forwarded to the recipient candidate or authorized committee pursuant to 11 CFR 102.8.

(iv) The report by the conduit or intermediary shall contain the following information:

(A) The name and mailing address of each contributor, and, for each earmarked contribution in excess of \$200, the contributor's occupation and the name of his or her employer;

(B) The amount of each earmarked contribution, the date received by the conduit, and the intended recipient as designated by the contributor; and

(C) The date each earmarked contribution was forwarded to the recipient candidate or authorized committee and whether the earmarked contribution was forwarded in cash or by the contributor's check or by the conduit's check.

(v) For each earmarked contribution passed through the conduit's or intermediary's account, the information specified in paragraph (c)(1)(iv)(A) through (C) of this section shall be itemized on the appropriate schedules of receipts and disbursements attached to the conduit's or intermediary's report, or shall be disclosed by letter, as appropriate. For each earmarked contribution forwarded in the form of the contributor's check or other written instrument, the information specified in paragraph (c)(1)(iv)(A) through (C) of this section shall be disclosed as a memo entry on the appropriate schedules of receipts and disbursements attached to the conduit's or intermediary's report, or shall be disclosed by letter, as appropriate.

(vi) Paragraph (c)(1) of this section shall not apply to occasional, isolated, or incidental physical transfers of checks or other written instruments payable to a candidate or his or her authorized committee. For purposes of this paragraph, "occasional, isolated, or incidental" means no more than \$1,000 is forwarded to any one candidate or authorized committee in a calendar

year.

(2) Reports by recipient candidates and authorized committees. (i) The recipient candidate or authorized committee shall report each conduit or intermediary who forwards one or more earmarked contributions which in the aggregate exceed \$200 in any calendar year.

(ii) The report by the recipient candidate or authorized committee shall contain the following information:

(A) The identification of the conduit or intermediary, as defined in 11 CFR 100.12;

- (B) The total amount of earmarked contributions received from the conduit or intermediary and the date of receipt; and
- (C) The information required under 11 CFR 104.3(a)(3) and (4) for each earmarked contribution in excess of \$200.
- (iii) The information specified in paragraph (c)(2)(ii)(A) through (C) of this section shall be itemized on Schedule A attached to the report for the reporting period in which the earmarked contribution is received.

(d) Direction and control over earmarked contributions.

(1) A conduit's or intermediary's contribution limits are not affected by the forwarding of earmarked contributions except where the conduit or intermediary exercises any direction or control over the choice of the recipient candidate or authorized committee.

(2) If a conduit or intermediary exercises any direction or control over the choice of the recipient candidate or authorized committee, the earmarked contribution shall be considered a contribution by both the original contributor and the conduit or intermediary. If the conduit or intermediary exercises any direction or control over the choice of the recipient candidate or authorized committee, the reports filed by the conduit or intermediary and the report filed by the recipient candidate or authorized committee shall indicate that the earmarked contribution is made by both the original contributor and the conduit or intermediary, and that the entire amount of the contribution is attributed to each.

Dated: July 23, 1986. Joan D. Aikens,

Chairman, Federal Election Commission. [FR Doc. 86–16997 Filed 7–29–86; 8:45 am] BILLING CODE 6715–01–M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

Small Business Size Standards; Arrangement of Passenger Transportation—Travel Agents

AGENCY: Small Business Administration. ACTION: Proposed Rule.

SUMMARY: SBA is proposing to amend its size standard regulation for the arrangement of passenger transportation or travel agent industry (SIC-4722). The proposed standard is \$500,000 in annual receipts measured by commissions, averaged over 3 years. This proposal would change the measure of firm size for travel agents from gross bookings to commissions. It would also increase the standard from the present \$3.5 million in bookings (\$350,000 in commissions) to \$500,000 in commissions only.

This action is being proposed because of the Government's recently initiated program to procure travel arrangements for its employees through travel agents. It is intended to more precisely define that segment of the industry which is small and to facilitate the participation

of small business in the procurement set-aside program.

DATE: Written comments must be submitted on or before September 29, 1986.

ADDRESS: Andrew A. Canellas, Director, Size Standards Staff, 1441 'L' Street NW., Room 601, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Harvey D. Bronstein, Economist, Size Standards Staff, (202) 653–6373.

SUPPLEMENTARY INFORMATION: Recent changes in Government procurement policy allow travel agents for the first time under contract with various Federal agencies to make travel arrangements for Government employees. These contracts are administered by the General Services Administration (GSA).

The current size standard, \$3.5 million, has been in effect since 1984. It was first proposed in 1983 before SBA became aware of impending changes in the Government's procurement policy. Also, there have been varying and conflicting interpretations by GSA, SBA program offices, and the SBA's Office of Hearings and Appeals as to whether the \$3.5 million in receipts means gross value of bookings or commissions. SBA's Office of Hearings and Appeals stated in a 1985 size appeal case that as the regulation is currently written (at 13 CFR 121.2) the size standard may mean commissions. As gross value of bookings is a multiple of commissions, the present size standard effectively may be equivalent to \$35 million in value of bookings, assuming a 10 percent commission. SBA believes that an effective size standard of this magnitude is unreasonably large.

In addition, SBA never intended to have such a high standard. SBA intended the \$3.5 million size standard to be measured in gross value of bookings. Upon reconsideration, SBA believes that a standard measured in commissions makes more sense. Accordingly, this proposed rule is needed to adjust the measurement of the travel agent size standard from gross bookings to commissions. At the same time, SBA proposes to amend the numerical value of the current size standard itself. When examining an industry to estalbish a size standard. SBA considers five primary factors: the extent of industry competition, average firm size, firm size distribution, startup costs, and Federal procurement. First, the structure of the travel agent industry is typically small business. While most travel agencies are single location business, there are a number of multibranch regional agencies and a few

nationwide firms. The larger firms, however, do not dominate the industry in the sense of having a few firms control a large share of industry sales. Thus the industry can be considered to be quite competitive.

Second, average firm size is 8 employees (full and part-time) and receipts as measured by gross value of bookings is \$1.4 million. Assuming a 10 percent commission on bookings, average receipts in terms of commissions is \$140,000. These averages are typical for industries characterized by small business.

Third, firm size distribution gives a more detailed picture of the industry's structure, especially when considered in conjunction with average firm size. There are over 16,000 firms in the industry. Over 90 percent of them fall below the current (\$3.5 million in bookings) size standard. Firms in this size range account for three-fourths of industry sales. Clearly, small firms dominate this industry.

Fourth, the startup costs in the travel agent industry are low. This contributes to the small business character of the industry and helps explain why the average firm size is low and the industry is so competitive.

Fifth, since 1984 the Government through the General Services Administration has been awarding contracts to travel agents to provide travel services to various Federal agencies. GSA plans ultimately to award about 250 contracts with a total bookings value of \$300 million. Thus, with average contract size of just over \$1 million, GSA has been setting aside many of the contracts for small business. To date most contracts have been averaging below \$500,000 each. Out of 133 contracts awarded through early 1986, only 44 have exceeded \$1 million in value.

Selection of Size Standard

\$3.5 million is the lowest size standard which SBA uses and serves as the starting point for establishing size standards in the services sector. Industries to which the \$3.5 million standard is applied are typically unconcentrated with low average firm size, low startup costs, highly competitive, and small business oriented. While the travel agent industry fits this description, it differs from other service industries in that value added or actual in-house efforts is low (about 10 percent of sales) compared to other industries.

For example, a firm in the services industries with \$3.5 million in sales would normally have far more employees than a travel agency with the

same sales. For services in general, a firm with \$3.5 million in sales would on average have 85 employees, in accounting and bookkeeping about 74 employees, and computer programming about 50 employees. A travel agent firm of \$3.5 million by comparison would only have approximately 20 employees. This argues for a somewhat higher size standard.

Second, average contract size of \$1.2 million when compared to the current size standard of \$3.5 million, appears large. One average size contract would represent one-third of the total sales of the maximum allowable size firm, and more of a smaller size firm. Considering contract size, a somewhat higher size standard would be appropriate so that contract size is not disproportionate to the size standard itself.

Because of the structure of this industry as described above, however, a large increase in the size standard would not be warranted. For example, a \$10 million size standard would not only include 99 percent of the industry's firms, but also about 80 percent of industry sales. Such a high inclusion rate would make a \$10 million size meaningless, as nearly the entire industry's output would come within the small business definition. While not a target for size standards purposes, the overall inclusion rate of sales for firms below the SBA size standards averages 40 percent across all industries.

Yet for the reasons indicated, SBA believes a moderately higher size standard is desirable. A \$5 million size standard would represent a modest increase. Such a firm in everyday terms, SBA estimates, would employ about 30 persons and do business from 3 or 4 locations. Under the current size standard, the eligible firm size would be represented by a firm with about 20 employees, with 2 or 3 locations.

Therefore, SBA is proposing to amend its regulations to establish a new size standard at \$5 million. However, to conform with commonly accepted accounting practices in this industry where receipts are based on commissions, a size standard of \$500,000 in commissions, roughly equivalent to \$5 million in gross value of bookings, is being proposed.

SBA certifies that this regulation, if promulgated in final form, will not have a significant adverse economic impact on a substantial number of small entitles within the meaning of the Regulatory Flexibility Act, 5 U.S.C. § 601 et seq. Because of the SBA's Office of Hearings and Appeals 1985 ruling that the \$3.5 million size standard may be commissions rather than gross bookings,

the impact of the proposed change can be viewed in two ways.

First, if viewed as commissions, the proposed change from \$3.5 million to \$500,000 in commissions is a decrease in the size standard. Consequently, about about 100 firms changing status from the small to the non small category.

Second, if the \$3.5 million is regarded as gross bookings, then the \$500,000, equivalent to \$5 million in gross bookings can be seen as an increase in the size standard. Consquently, about one or two hundred firms would gain small business status. However the change is regarded, since not all firms and in fact only a minority of firms are typically interested in Government procurement, the actual impact would be smaller than these estimates indicate.

A secondary impact is the one which normally occurs whenever any size standard is changed; that is, when a standard is increased, the firms below the former size standard are confronted with a new group of potential competitors for set-aside procurements. This may adversely affect those firms below the former size standard. On the other hand, when a size standard is decreased, the firms between the old and new size standards lose small business status. The remaining smaller firms gain by having fewer potential competitors on set-aside procurements.

SBA also certifies that this regulation is a nonmajor rule as defined by Executive Order No. 12291, in that it is not expected to have an impact of over \$100 million per year. In addition, this regulation is not likely to result in a major increase in costs of prices, or have a significant adverse impact on the U.S. economy. The level of Government contracts in the travel agent industry was \$188 million as of early 1986. These contracts will continue to be made, regardless of the size standard. The clarification of receipts being measured in commissions rather than gross bookings will have no impact on costs, prices, or the U.S. economy. The slight change from \$350 thousand (the intended \$3.5 million in gross bookings) to \$500 thousand in commissions is also not likely to have a \$100 million effect or to increase costs or prices in any way.

SBA certifies that this regulation contains no reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C., Chapter 35.

This rule defines the maximum size firm in the industry which may be eligible for SBA assistance. The legal basis for this proposal is section 5(b) of the Small Business Act, U.S.C. 634(b). There are no Federal rules which

duplicate, overlap, or conflict with the proposed rule.

List of Subjects in 13 CFR Part 121

Administrative practice and procedure, Government procurement, Government property, Grant Programs-business, Loan programs-business, Recording and recordkeeping requirements, Small business.

PART 121-[AMENDED]

Accordingly, SBA proposes to amend Part 121 of 13 CFR as follows:

1. The authority citation for Part 121 continues to read as follows:

Authority: 15 U.S.C. 634(b).

§ 121.2 [Amended]

2. In § 121.2(c)(2), Major Group 47-Transportation Services, SIC 4722 is revised as follows:

4722 Arrangement of Passenger Transportration \$500,000 commissions

Dated: July 11, 1986. Charles L. Heatherly,

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Acting Administrator, Small Business Administration.

[FR Doc. 86-17093 Filed 7-29-86; 8:45 am]

13 CFR Part 125

Breakout Procurement Center Representative Program, Extension of Comment Period

AGENCY: Small Business Administration.
ACTION: Notice of proposed rulemaking;
extension of comment period.

SUMMARY: The Small Business Administration (SBA) proposes to issue regulations governing the Breakout Procurement Center Representative Program at Federal Government procurement centers. These regulations implement the passage of the Small **Business and Federal Procurement** Competition Enhancement Act of 1984 which authorized the placement of SBA Breakout Procurement Center Representatives at major procurement centers. The proposed regulations were published in the Federal Register on June 27, 1986 (51 FR 23426). The original date for submission of comments was July 28, 1986. In response to requests to extend the comment period, the SBA has decided to extend the period for public comment to ensure the adequacy of the time made available for public consideration of the proposed regulations.

DATE: Written comments should be submitted on or before August 27, 1986. ADDRESS: Comments may be addressed to Roy Rodgers, Director, Office of Prime Contracts, Small Business Administration, 1441 L Street NW., Washington, DC, 20416.

FOR FURTHER INFORMATION CONTACT: Scott Denniston (202) 653-6485.

Dated: July 21, 1986.
Charles L. Heatherly,
Acting Administrator.
[FR Doc. 86–17092 Filed 7–29–86; 8:45 am]
BILLING CODE 8025–01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 86-CE-07-AD]

Airworthiness Directive: Mitsubishi Heavy Industries, Limited, Models MU-2B, MU-2B-10, MU-2B-15, MU-2B-20, MU-2B-25, MU-2B-26, MU-2B-30, MU-2B-35, and MU-2B-36 Airplanes

AGENCY: Federal Aviation
Administration (FAA), DOT.
ACTION: Notice of proposed rulemaking
(NPRM).

SUMMARY: This Notice proposes to supersede Airworthiness Directives (ADs) 74-11-02 (Amendments 39-1846, 39-2269) and 75-02-01 (Amendments 39-2059, 39-2269) applicable to certain Mitsubishi Heavy Industries, Limited, (MHI) Type Certificate A2PC Models MU-2B, -10, -15, -20, -25, -26, -30, -35, and -36 airplanes which would eliminate the repetitive inspections of these AD's and require a one time inspection, sealing or replacement, as necessary, of wing flap flexible shafts as well as shaft routing adjustment for bend radius relief. The proposed superseding AD is needed because the FAA has learned of additional wing flap flexible shaft failures. Failure of the wing flap flexible shaft will result in aircraft roll upon operation of flaps during flight. This proposed action will preclude wing flap flexible shaft failure. DATES: Comments must be received on or before September 2, 1986.

ADDRESSES: MHI Service Bulletin (S/B) MU-2 No. 198 dated February 13, 1985, applicable to this AD, may be obtained from Mitsubishi Heavy Industries, Ltd., 10, Oye-Cho, Minato-ku, Nagoya, Japan, or Beech Aircraft Corporation, 9709 East Central, Post Office Box 85, Wichita, Kansas 67201.

Send comments on the proposal in duplicate to Federal Aviation Administration, Central Region, Office of the Regional Counsel; Attention: Rules Docket No. 86–CE–07–AD, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8:00 a.m. and 4:00 p.m. Monday through Friday, holidays excepted.

FOR FURTHER INFORMATION CONTACT: Mr. Charles Richard, Aerospace Engineer, Airframe Section, ANM– 172W, Western Aircraft Certification Office, Northwest Mountain Region, FAA, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009– 2007; Telephone (213) 297–1374.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will considered by the Director before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. Comments are specifically invited on the overall regulatory, economic, environmental, and emergency aspects of the rule. All comments submitted will be available both before and after the closing date for comments in the Rules Docket for examination by interested persons. A report summarizing each FAA public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Central Region, Office of the Regional Counsel; Attention: Airworthiness Rules Docket No. 86–CE–07–AD, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

Discussion

The manufacturer has a report that a wing flap flexible shaft has failed on a MU–2B airplane prior to the manufacturer's recommended maximum service life of 2000 hours. As a result, MHI has issued MU–2B S/B No. 198 dated February 13, 1985, which gives instructions for a torque inspection and a sealing process on flap flexible shaft joints. These instructions are more effective than inspections required by AD 74–11–02 and AD 75–02–01. The

Japan Civil Aviation Bureau, which has responsibility and authority to maintain the continuing airworthiness of these airplanes in Japan, has classified this service bulletin and the actions recommended therein by the manufacturer as mandatory and has issued (Japanese) AD TCD-2451-85 to assure the continued airworthiness of the affected airplanes. On airplanes operated under Japanese regulations, this action has the same effect as an AD on airplanes certificated for operation in the United States.

Consequently, the proposed AD is applicable to MHI Models MU-2B, -10, -15, -20, -25, -26, -30, -35, and -36 airplanes and would require inspection, sealing of joints, and replacement, if necessary, of the flap flexible shaft in accordance with MHI MU-2, S/B No. 198 and removal of flap drive shaft clamp at W.S. 2590 to allow routing of flap flexible shaft to relieve any bend radius less than 8.7 inches and the elimination of the recurrent required 100 hours time-in-service (TIS) inspections. In addition, the affected flap flexible shaft part numbers are now RY25-1 or 8022Y-OC-97.00, or 8022Y-OC-97.50 or 035A-961001-3. These actions are to preclude operational failure of the wing flaps.

There are approximately 388 United States registered airplanes affected by this proposed AD. The cost of complying with this proposed AD is estimated to be \$240 per airpline. The cost to the private sector is estimated to be \$93,120. Few, if any, small entities own the affected airplanes. The cost of compliance is so minimal that it would not impose a significant economic burden on any such owner.

Therefore, I certify that this action (1) is not a major rule under the provisions of Executive Order 12291, (2) is not a significant rule under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979), and (3) if promulgated, will not have a significant economic impact on a substantial number of small entities under this criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation has been prepared for this action and has been placed in the public docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES."

List of Subjects in 14 CFR Part 39

Air Transportation, Aviation Safety, Aircraft, Safety.

The Proposed Amendment

PART 39-[AMENDED]

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); 14 CFR 11.89

2. By superseding AD 74–11–02 (Amendment 39–1846 as amended by Amendment 39–2269) and AD 75–02–01 (Amendment 39–2059 as amended by Amendment 39–2269) with the following new AD.

Mitsubishi Heavy Industries, Ltd.

Applies to Type Certificate A2PC Models MU-2B, MU-2B-10, MU-2B-15, MU-2B-20, MU-2B-25, MU-2B-26 (Serial Nos. (S/Ns) 008 through 347 except S/Ns 313 and 321); MU-2B-30, MU-2B-35, MU-2B-36 (S/Ns 501 through 696 except S/Ns 652 and 661), certificated in any category. The proposed AD would not apply to MU-2B series airplanes having serial numbers with "SA" suffix.

Compliance: Required as indicated in the body of the AD unless previously accomplished.

To preclude failure of flap flexible shaft Part Nos. (P/N) RY25-1, or 8022Y-OC-97.00, or 8022Y-OC-97.50, or 035A-961001-3, and potential split flap operation, accomplish the following:

(a) For flap flexible shafts with less than 1000 hours of time in service (TIS) on the effective date of this AD:

(1) Within the next 100 hours of TIS, seal the fitting and the connection area of the flap flexible shaft in accordance with "INSTRUCTIONS" of MHI MU-2 Service Bulletin (S/B No. 198 dated February 13, 1985.

(2) Prior to the accumulation of 1100 hours total TIS of the flap flexible shaft, perform torque inspection and seal the fitting and the connection area of the flap flexible shaft in accordance with the MHI MU-2 S/B No. 198, referenced in paragraph (a)(1) of this section.

(b) For flap flexible shafts with 1000 or more hours of TIS on the effective date of this AD: Within 100 additional hours TIS perform the torque inspection, and seal the fitting and the connection area of the flap flexible shaft in accordance with MU-2 S/B No. 198, as referenced in paragraph (a)(1) of this section.

(c) Before further flight, remove from service flap flexible shafts that do not meet the torque requirements stated in MHI MU-2 S/B No. 198, and replace these shafts in accordance with paragraph (d) of this AD.

(d) Prior to installing a new flexible shaft, seal the new part in accordance with MU-2 S/B No. 198, referenced in paragraph (a)(1) of this section

(e) Within 100 hours of TIS after the effective date of this AD, remove and do not reinstall the clamp at W.S. 2590 and assure

that the flap flexible shaft is installed so as to establish that no bend radius througout the length of the shaft between W.S. 2370 and W.S. 2910 is less than 8.7 inches (220 millimeters.).

(f) Special flight permits may be issued in accordance with FAR 21.197 and FAR 21.199 to ferry aircraft to a maintenance base in order to comply with the requirements of this

AD.

(g) An equivalent method of compliance with this AD may be used when approved by the Manager of the Western Aircraft Certification Office, Northwest Mountain Region, FAA, Post Office Box 92007, Worldway Postal Center, Los Angeles, California 90009–2007.

All persons affected by this directive may obtain copies of the document(s) referred to herein upon request to Mitsubishi Heavy Industries, Ltd., 10, Oye-Cho, Minato-Ku, Nagoya, Japan, or Beech Aircraft Corporation, 9709 East Central, Post Office Box 805, Wichita, Kansas 67201, or FAA, Office of the Regional Counsel, Room 1558, 601 East 125th Street, Kansas City, Missouri 64106.

This amendment, if promulgated, will supersede AD 74–11–02 (Amendment 39–1846 (39 FR 17220) as amended by Amendment 39–2269 (40 FR 30464)) and AD 75–02–01 (Amendment 39–2059 (39 FR 44740) as amended by Amendment 39–2269 (40 FR 30464)).

Issued in Kansas City, Missouri, on July 18, 1986.

Edwin S. Harris,

Director, Central Region.

[FR Doc. 86-17019 Filed 7-29-86: 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 134

Country-of-Origin Marking Requirement for Imported Fruit Juice Concentrate

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Proposed interpretive rule; solicitation of public comments on effective date.

SUMMARY: This notice is to advise the public that Customs is extending to other imported fruit juice concentrate undergoing similar processing, the ruling which held that imported orange juice concentrate which is used in the production of frozen concentrated or reconstituted orange juice is not substantially transformed or reconstituted orange juice is not substantially transformed after undergoing further processing in the U.S. (blending with other batches of

concentrate, water, oils and essences, pasteurization or freezing and repacking). Accordingly, labels on these frozen concentrated and reconstituted fruit juice products which contain imported concentrate will have to be marked to indicate the foreign country-of-origin of the products. Customs is seeking public comments on the date this requirement should become effective. All comments received will be considered before reaching a decision on this issue.

DATE: Comments (preferably in triplicate) must be received on or before September 29, 1986.

ADDRESS: Comments may be submitted to and inspected at the Regulations Control Branch, U.S. Customs Service, Room 2426, 1301 Constitution Avenue, NW., Washington, DC 20229 (202–566–8237).

FOR FURTHER INFORMATION CONTACT: Lorrie Rodbart, Entry Procedures and Penalties Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, DC 20229 (202–566–5765).

SUPPLEMENTARY INFORMATION:

Background

In response to a formal request, Customs published a ruling dated September 4, 1985, in the Customs Bulletin of September 25, 1985 (C.S.D. 85-47, 19 Cust. Bull. No. 39 at 21), stating that containers of orange juice in frozen concentrated or reconstituted forms. which contain imported concentrate, must be labled to comply with the country-of-origin marking requirements of section 304, Tariff Act of 1930, as amended (19 U.S.C. 1304). The ruling was based on the determination that the imported concentrate which is used in the production of frozen concentrated or reconstituted orange juice is not substantially transformed after undergoing further processing in the U.S. including blending with other batches of concentrate, water, oils and essences, pasteurization or freezing, and repacking. In a case brought by the National

Juice Products Association, et al. challenging C.S.D. 85-47, National Juice Products Association v. United States, CIT Slip Op. 86-13 (January 30, 1986), the Court of International Trade held that C.S.D. 85-47 was substantively valid. The Court, however, remaned the case to Customs for reconsideration of the effective date. The Court directed Customs to adhere to the notice and comment provisions of § 177.10(c)(2), Customs Regulations (19 CFR 177.10(c)(2)), and to carefully consider all possible issues relating to a reasonable time to implement the new ruling. Accordingly, by notice published

in the Federal Register on March 3, 1986 (51 FR 7285), Customs solicited the views of the public on the issue of a reasonable implementation date. Comments received in response to that notice were considered. The public was advised of the February 1, 1987, effective date of C.S.D. 85–47 by publication of T.D. 86–120 in the Federal Register of June 25, 1986 (51 FR 23045).

Customs is of the opinion that the principles set forth in C.S.D. 85-47 are also applicable to other fruit juice products and is therefore extending the orange juice ruling to all other imported fruit juice consentrates which undergo processing in the U.S. similar to that performed with regard to orange juice.

Customs is seeking public comments related solely to the issue of the best practicable implementation date for the new requirement that frozen concentrated or reconstituted fruit juices which contain imported content be labeled to reveal that content. Of particular interest is any information concerning the time it generally takes suppliers to provide new or changed labels and containers to the packagers of juice products, as well as the quality of labels and printed retail containers usually kept in inventory.

Comments

Before making a determination on this matter, Customs will consider any written comments timely submitted. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), between 9 a.m. and 4:30 p.m. on normal business days, at the Regulations Control Branch, Room 2426, U.S. Customs Service Headquarters, 1301 Constitution Avenue NW., Washington, DC. 20229.

Drafting Information

The principal author of this document was Larry L. Burton, Regulations Control Branch, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

Alfred R. De Angelus,

Acting Commissioner of Customs. Approved: July 14, 1986.

Francis A. Keating, II,

Assistant Secretary of the Treasury.

[FR Doc. 86–17074 Filed 7–29–86; 8:45 am]

BILLING CODE 4820–02-M

19 CFR Part 175

Receipt of Domestic Interested Party Petition Concerning Classification of Orange Juice Concentrate-Based Product

AGENCY: U.S. Customs Service, Department of the Treasury. ACTION: Proposed interpretive rule; solicitation of comments.

SUMMARY: Customs has received a petition submitted on behalf of a domestic interested party with respect to a Customs ruling that an orange juice concentrate-based product consisting of orange juice concentrated to 65° Brix to which certain ingredients were added was classified under item 183.05, Tariff Schedules of the United States (TSUS). as other edible preparations, not specially provided for. The petitioner contends that the subject product should be classified under item 165.29, TSUS, as concentrated orange juice or orange juice made from concentrated orange juice. The petitioner argues that orange juice is now provided for eo nomine in the TSUS because of an amendment by the Trade and Tariff Act of 1984 (Pub. L. 98-573). This document invites comments with respect to the correctness of the classification.

DATE: Comments must be received on or before September 29, 1986.

ADDRESS: Comments (preferably in triplicate) may be addressed to and inspected at the Regulations Control Branch, U.S. Customs Service, 1301 Constitution Avenue NW., Room 2426, Washington, DC 20229 (202–566–8237).

FOR FURTHER INFORMATION CONTACT: Thomas L. Lobred, Classification and Value Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, DC 20229 (202–566–8181).

SUPPLEMENTARY INFORMATION:

Background.

Pursuant to section 516, Tariff Act of 1930, as amended (19 U.S.C. 1516), a domestic interested party petition has been filed with respect to a decision in which Customs ruled that an orange juice concentrate-based product consisting of orange juice concentrated to 65° Brix to which certain ingredients were added was classified under item 183.05, Tariff Schedules of the United States (TSUS) (19 U.S.C. 1202).

On July 26, 1984, Customs issued ruling 553167 (C.S.D. 84–117, 18 Cust. B. and Dec. No. 49 at 43, December 5, 1984), which stated that a product consisting of 87 percent orange juice concentrate (65° Brix), 10.5 percent orange peel extract, 2.25 percent citrus acid and less than one percent total of sodium benzoate, orange oil and artificial color was properly classifiable under the provision for other edible preparations, not specially provided for, in item 183.05, TSUS

In this ruling, Customs dismissed classification under item 166.40, TSUS, as beverages, not specially provided for, and item 165.35, TSUS, as other citrus fruit juice concentrate (now item 165.36, TSUS). Customs did not find item 166.40, TSUS, applicable because Headnote 1, schedule 1, part 12, subpart B, TSUS, indicates that item 166.40, TSUS, only covers products fit for use as beverages, and the subject product is not, in its condition as imported, potable and ready to consume. Classification under item 165.35, TSUS, was stated to be precluded because the subject product was not within the common or commercial understanding of orange juice concentrate, having been processed beyond the scope thereof by the addition of significant and substantial "foreign" or excess ingredients.

On October 17, 1985, a petition was submitted on behalf of a domestic interested party representing domestic citrus growers. The petitioner challenges the tariff classification holding in C.S.D. 84-117. The petition states that the tariff provision relating to fruit juices was amended by section 117 of the Trade and Tariff Act of 1984 (Pub. L. 98-753), to include in new items 165.27 and 165.29, TSUS, an eo nomine provision for orange juices, both in natural and in

all other forms.

The petitioner argues that the basic principles of tariff classification require that the subject product be classified under item 185.29, TSUS, because an eo nomine designation such as item 185.29, TSUS, without limitation or shown contrary legislative intent, judicial decision or administrative practice, and without proof of commercial designation, will include all forms of the article. The mere fact that there may be some added ingredients does not preclude its classification in the eo nomine provision. It is argued that the added ingredients do not alter the subject product's essential character as orange juice concentrate.

The petitioner also argues that Customs definition of orange juice, which is adopted from FDA's standards of identity, is questionable as FDA regulations should not define or determine the common meaning of the term for tariff purposes.

Comments

Pursuant to § 175.21(a), Customs Regulations (19 CFR 175.21(a)), before making a determination on this matter, Customs invites written comments from interested parties on this issue. The domestic interested party petition, as well as all comments received in response to this notice, will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m. at the Regulations Control Branch, Room 2426, Customs Headquarters, 1301 Constitution Avenue, NW., Washington, DC 20229.

Authority

This notice is published in accordance with § 175.21(a), Customs Regulations (19 CFR 175.21(a)).

Drafting Information

The principal author of this document was Harold M. Singer, Regulations Control Branch, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

Approved: July 14, 1986.

Alfred R. De Angelus,

Acting Commissioner of Customs.

Francis A. Keating, II,

Assistant Secretary of the Treasury.
[FR Doc. 86-17075 Filed 7-29-86; 8:45 am]
BILLING CODE 4820-02-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701, 842, and 843

Availability of Petition To Initiate Rulemaking; Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Federal Inspection and Enforcement Authority

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Notice of availability of petition to initiate rulemaking and request for comment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSMRE) seeks comments regarding a petition submitted by the Mining and Reclamation Council of America and the Regulatory assistance Program comprised of ten State coal associations. The petition was submitted pursuant to the Surface Mining Control and Reclamation Act the (the Act) to amend

OSMRE's existing regulations concerning Federal inspections and enforcement when a State regulatory program is in effect and to establish uniform standard review procedures for evaluating state responses to ten-day notices. The petitioners maintain that the proposed amendments and modification will conform OSMRE's permanent program regulations to the plain language of the statute, Congressional intent and existing case law.

OSMRE is requesting comments on the merits of the petition and the rule changes suggested in the petition. Such comments will assist the Director of OSMRE in making a decision to grant or deny the petition.

OSMRE on January 3, 1986, announced receipt of, and solicited public comment on a petition from ten citizen organizations regarding OSMRE's Criteria and Procedures for substituting Federal enforcement for or withdrawing Federal approval of a State regulatory program under SMCRA. OSMRE is announcing in a separate Federal Register notice a reopening of the comment period on certain aspects of that petition.

OSMRE is also announcing its intent to hold a conference during the comment period, for the purpose of exchanging views on the effectiveness of the agency's use of ten-day notices and Federal notices of violation (NOV's) and on the criteria for substituting Federal enforcement for, or withdrawing State primacy under SMCRA. The conference proceedings and relevant supporting documents will be entered into the administrative record on the MARC petition announced here, the petition announced January 3, 1986, or both as appropriate. Further information on the conference will be announced in the Federal Register shortly.

DATE: OSMRE will accept written comments on the petition until 5:00 p.m. daylight savings time on September 29, 1986.

ADDRESSES: Written comments should be mailed to the Administrative Record, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue, NW., Washington, DC 20240, or hand-delivered to the administrative record, Office of Surface Mining, U.S. Department of the Interior, Room 5124, 1100 "L" Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Murray Newton, Acting chief, Division of Regualtion and Inspection, Office of Surface Mining Reclamation and Enforcement, Constitution Avenue, NW., Washington, DC 20240. Telephone: (202) 343–4295.

SUPPLEMENTARY INFORMATION: .

I. Public Comment Procedures

Written Comments

Written comments on the suggested changes should be specific, should be confined to issues pertinent to the petition, and should explain the reasons for the comment. Comments received after the close of the comment period (see "DATES") may not necessarily be considered or included in the administrative record on the petition. OSMRE cannot ensure that written comments received or delivered during the comment peirod to any location other than that specified under "ADDRESSES" above will be considered and included in the administrative record on this petition.

Availability of Copies

Additional copies of the petition and copies of 30 CFR Parts 701, 842 and 843 are available for inspection and copying at the location listed under "ADDRESSES."

Public Meetings

As stated above, a conference will be held on the agency's use of ten-day notices and Federal NOV's. Although, OSMRE will not hold a public hearing on the petition, OSMRE personnel will be available to meet with the public during business hours, 8:00 a.m. to 4:00 p.m., during the comment period. In order to arange such a meeting on the petition, call or write to the person listed above under "FOR FURTHER INFORMATION CONTACT."

II. Background and Substance of Petition

OSMRE received a letter dated May 30, 1986, from Mr. Daniel R. Gerkin, President of the Mining and Reclamation Council of America transmitting a petition for rulemaking on behalf of the Mining and Reclamation Council of America, and the Regulatory Assistance Program comprised of the Alabama Coal Association, Coal Operators and Associates, Facts About Coal in Tennessee, Illinois Coal Association. Indiana Coal Council, Kentucky Coal Association, the Ohio Coal and Energy Association, Ohio Mining and Reclamation Association, Pennsylvania Coal Mining Association and West Virginia Mining and Reclamation Association. The petitioners seek certain amendments and modifications to regulations found at 30 CFR Parts 701, 842 and 843 relating to Federal

inspections and enforcement when a State regulatory program is in effect, and ask that OSMRE establish uniform standard review procedures for evaluating State responses to ten-day notices. The text of the petition appears as an appendix to this notice.

Pursuant to section 201(g) of the Act, any person may petition for a change in OSMRE's permanent program rules which appear in 30 CFR Chapter VII. The Act allows for a period of 90 days within which to decide to grant or deny a petition (section 201(g)(4); 30 U.S.C. 1211(g)(4)). Under the applicable regulations for rulemaking petitions, 30 CFR 700.12, this notice seeks public comments on the merits of the petition and on the rule changes suggested in the petition. At the close of the comment period, a decision will be made to grant or deny the petition. If a decision is made to grant the petition, rulemaking proceedings will be initiated in which public comment will again be sought before any final rulemaking. If a decision is made to deny the entire petition, no further rulemaking action will occur pursuant to the petition.

OSMRE is publishing this petition because of the public interest on this topic. In the event a decision is made to deny the petition and not to issue a proposed rule, publication of this notice is not intended to waive any Departmental defenses under section 526 of the Act, 30 U.S.C. 1276, or to allow a petition unilaterally submitted for repeal of a regulation to create the basis for a review of a regulation which may not otherwise be challenged.

III. Procedural Matters

Publication of this notice of the receipt of the petition for rulemaking is a preliminary step prior to commencement of the rulemaking process. If a decision is made to grant the petition, a rulemaking process will be initiated. Thus, no regulatory flexibility analysis is needed at this stage, nor is a regulatory impact analysis necessary under Executive Order No 12291.

Publication of this notice does not constitute a major Federal action having a significant effect on the human environment for which an environmental impact statement under the National Environmental Policy Act, 42 U.S.C. 4322(2)(C), is needed.

List of Subjects

30 CFR Part 701

Law enforcement, Surface mining, Underground mining.

30 CFR Part 842

Law enforcement, Surface mining, Underground mining.

30 CFR Part 843

Administrative practice and procedure, Law enforcement, Reporting and recordkeeping requirements, Surface mining, Underground mining.

Dated: July 23, 1986. Jed D. Christensen, Director.

Appendix

The text of the petition dated May 30, 1986, from the Mining and Reclamation Council of America and the Regulatory Assistance Program is as follows:

Petition to initiate rulemaking: 30 CFR 700.12.

Petition for Rulemaking

Office of Surface Mining

Submitted by:

Mining and Reclamation Council of America
Regulatory Assistance Program comprised of:
Alabama Coal Association
Coal Operators and Associates
Facts About Coal In Tennessee
Illinois Coal Association
Indiana Coal Council
Kentucky Coal Association
The Ohil Coal and Energy Association
Ohio Mining and Reclamation Association
Pennsylvania Coal Mining Assocation
West Virginia Mining and Reclamation
Assocation

I. Summary

Pursuant to the Administrative Procedure Act, 5 U.S.C. 553(e), the surface Mining Control and Reclamation Act of 1977, (SMCRA or the Act), 30 U.S.C. 1211(c)(2) and (g), and regulations of the Office of Surface Mining Reclamation and Enforcement (OSMRE), 30 CFR 700.12, the Mining and Reclamation Council of America, and the Regulatory Assistance Program comprised of the Alabama Coal Association, Coal Operators and Associates, Facts About Coal in Tennessee, Illinois Coal Association, Indiana Coal Council, Kentucky Coal Association, The Ohio Coal and Energy Association, Ohio Mining and Reclamation Association, Pennsylvania Coal Mining Association and West Virginia Mining and Reclamation Association (collectively the "Petitioners") petition the Director, OSMRE, for certain amendments and modifications to regulations contained in 30 CFR Parts 701, 842 and 843 relating to Federal inspections and enforcement when a State regulatory program is in effect. The proposed amendments and modifications will conform OSMRE's

permanent program regulations to the plain language of the statute, Congressional intent and existing case law.

II. Description of Petitioners

The Mining and Reclamation Council of America is a national trade association representing coal producers of all sizes, ancillary industries and State and regional coal associations throughout the United States. Comprised of the ten aforementioned State coal associations, the basic purpose of the Regulatory Assistance Program is to represent members' views on the issues involving the States' primary regulatory authority under the Surface Mining Act and OSMRE's role in overseeing the implementation of approved State programs. The primary function of each individual petitioner is to assist its members in public issues surrounding coal mining and to cooperate with public authorities in dealing with those

III. Proposed Amendments and Modifications

Petitioners request the following amendments and modifications to the permanent program regulations relating to Federal inspection and enforcement when an approved state regulatory program is in effect.

 Repeal 30 CFR 701.4(b)(3).
 Amend 30 CFR 842.11 by adding new subsection (c) to read as follows:

(c) In making a determination under paragraph (b)(1)(ii)(B) of this section, the state regulatory authority will not be deemed to have failed to either take appropriate action to cause said violation to be abated or show good cause for such failure, unless a finding is made that the response or action of the state regulatory authority was arbitrary and capricious and an abuse of its discretion under the applicable state program.

Renumber existing paragraphs (c) and (d) to (d) and (e) respectively.

3. Repeal 30 CFR 843.12(a)(2). Renumber paragraph (a)(1) of that section (a).

4. Delete the term "notice of violation" from 30 CFR 843.17.

IV. Statement of Facts and Law In Support of Amendment and Modification of Existing Federal Inspection and Enforcement Regulations

A. Background

One of the most serious flaws in OSM's present oversight policy rests with the agency's reflexive use of notices of violation (NOV) when legitimate disputes exist between the state and OSM with respect to the accepted interpretation of the approved state program, differences in subjective judgment as to existing conditions at a mine operation and identified deficiencies in the state program approved by the Secretary as well as permits issued pursuant to the approved program. All too often operators have found themselves subject to federal enforcement action when following the program interpretation announced by the state regulatory authority, or relying upon the permit issued by state regulatory authority and inspections which indicate that the operation was in compliance with the approved program. Through the arbitrary substitution of its judgment for that of the states, and the circumvention of existing procedures to resolve interpretational disputes and program deficiencies, OSM has completely undermined the federalist scheme set forth in the statue in contervention of express congressional intent. OSM should not be focusing its limited resources in areas dealing with discretionary judgment, but addressing other areas where a complete breakdown of the program becomes clearly evident. In other words, OSM's reliance upon its purported NOV authority in primacy states has led to the use of citations to substitute its judgment for the states on a case-bycase basis through federal enforcement actions, with a corresponding reluctance to take decisive and comprehensive action in the face of a systemic breakdown in the administration of a state program. Petitioners submit that both policy reasons and applicable principles of statutory construction lead to the conclusion that absent the invocation of section 521(b), the Surface Mining Act does not authorize the issuance of federal NOV's in states with approved regulatory programs.

B. Administrative History

While the courts have only recently addressed OSM's direct enforcement authority in primacy states, the administrative history of the issue reveals a lingering doubt in the agency's own mind as to its statutory authority to issue NOVs during the permanent program. The proposed permanent program regulations did not provide for federal NOVs in primacy states. 43 FR 41930 (September 18, 1978). The preamble explained that the proposed regulation:

Only allows a Federal inspector to issue a notice of violation as part of the enforcement of a Federal Program, Federal lands program or during enforcement of a State program pursuant to sections 504(b) or 521(b) of the Act.

The preamble further explained the function of oversight inspections and ten-day notices as follows:

A violation (which is not an imminent hazard) which is observed during a Federal inspection in connection with evaluation of a state program . . . should be reported in writing to the state regulatory authority and the person responsible for the violation but that no notice of violation may be issued.

43 FR 41795 (September 18, 1978).

The final regulation adopted a different approach by providing for federal NOVs where the state refused or failed to take appropriate action. The preamble acknowledges that section 521(a)(3), does not authorize the regulatory solution adopted, but suggested that there existed a "statutory gap" which the agency should fill. 44 FR 15302 (March 13, 1979). The preamble to the final rules again explained the regulatory alternative, which was the original proposal, as providing for mere reporting of violations to the regulatory authority, with the only exception allowing for federal NOVs when OSM is formally "enforcing the state program pursuant to section 504(b) or section 521(b)." Id. Even without the authority to issue NOVs, federal inspections would serve the purpose of allowing OSM to "gather information for a section 521(b) proceeding (OSM taking over all or a portion of a state program)." Id.

Nevertheless, there was a perceived fear that without NOV authority, alleged violations would ripen into imminent hazards before OSM could take action pursuant to sections 504(b) and 521(b). Accordingly, relying merely upon what it admittedly characterized as "conflicting statements" in the legislative history, OSM chose to fill a perceived "void or gap" in the statute. The sole legal authority cited was a ruling by Judge Flannery in the 1978 interim program litigation which has no application to this issue. See, 44 FR 15302.1

Two years later, OSM revisited the issue, and proposed a regulation deleting the last sentence of 30 CFR 843.12(a)(2) which authorized federal NOVs in the oversight of state programs. 46 FR 58471 (December 1, 1981). OSM stated that:

¹ The regulations at issue in Judge Flannery's ruling concerned water quality performance standards which Congress did not explicitly address. Here, Congress squarely dealt with the issue concerning OSM's NOV authority. Moreover, the Court of Appeals reversed Judge Flannery's ruling with respect to filling the so-called "regulatory gap" for water quality standards. In Resultance Mining Regulation Litigation, 627 F. 2d 1346, 1366–69 (D.C. Cir. 1980).

[W]here a state has failed to take appropriate action to ensure abatement of a violation. OSM's recourse may be with the state rather than the permittee. The Office believes that, where an approved progam is in force, OSM may lack authority to issue citations directly to permittees except in those limited circumstances where public health and safety or significant imminent environmental harm would justify the issuance of a cessation order under section 521(a)(2) of the Act. The reinspection provided for in 30 CFR 843.12(a)(2) may simply be for the purpose of evaluating a state's performance under its approved program, rather than enforcing the Act directly against permittees.

46 FR 58467 (December 1, 1981).

OSM deferred further action on the proposal pending the completion of a supplemental Environmental Impact Statement (EIS) for the agency's regulatory reform efforts. 47 FR 17269 (April 21, 1982). Later, the agency reopened the comment period. 47 FR 20631 (May 13, 1982). On August 16, 1982, OSM published a final rule adopting several changes to the federal enforcement regulations, yet again deffered action of § 843.12 in order to further study the issue "in the context of the supplemental Environmental Impact Statement." 47 FR 35630.

In January 1983, OSM released its supplemental EIS. In examining the relative impacts of alternative A (retaining NOV authority) and alternative C (no NOV authority in oversight), the EIS detected some difference in impacts, yet concluded that "the difference would be insignificant." Final Environmental Impact Statement OSM EIS-1: Supplement, Vol 1: Analysis at IV-76 (January 1983). Despite this conclusion, OSM published a statement of policy summarily stating that 30 CFR 843.12(a)(2) was "properly and lawfully promulgated." 48 FR 9199 (May 3, 1983). The published policy statement did not engage in any new analysis, and offered the earlier flawed "fill the gap" rationale. The policy statement offered the same "conflicting" legislation history as the only legal basis for OSM's reaffirmation.

Indeed it appears today that the same legislative history cited by OSM was hardly conflicting, but instead, read completely out of context from both the statutory scheme and the specific enforcement, state and federal program provisions. In the meantime, a growing body of case law has rejected OSM's approach to oversight as embodied in 30 CFR 843.12(a)(2). Significantly, OSM's Management Action Plan tactitly acknowledges that OSM's employment of NOV's in oversight has been missued and is inappropriate.

C. The Surface Mining Act Does Not Authorize Federal Notices of Violation in States With Permanent Regulatory Programs Approved by the Secretary

1. State Program Approval

States administer and implement the federal Surface Mining Act through an approved state program. The Secretary's approval of a state program constitutes a decision that the program, with its acceptable variances for local conditions, will effectively implement the federal law within that state. 30 U.S.C. 1253; 30 CFR 732.13(i). In keeping with Congress' express finding that the primary governmental responsibility for issuing and enforcing regulations rests with the states, 30 U.S.C. 1201(b), the statute explicitly provides that upon program approval a state "assumes exclusive jurisdiction over the regulation of surface coal mining and reclamation operation." 30 U.S.C. 1253(a). This provision provides three limited exceptions to the "exclusivity" of state regulation. The most prominent being the listing of section 521, 30 U.S.C. 1271, which has been construed by OSM as its authority of issuing NOV's after approval of a state program. This limited exception, which properly construed preserves noting more than OSM's ability to take direct enforcement action after the proper exercise of Section 521(b), has been distorted to enable OSM to perpetuate its concurrent interim program authority during the permanent program.

2. Case Law

One of the early discourses by the judiciary on the role of the Secretary and States under the Surface Mining Act discloses a conspicuous absence of federal NOV authority, yet no perceived statutory gap inasmuch as "the Secretary's ultimate power over lax state enforcement is set out in Section 521(b)." In Re: Permanent Surface Mining Regulation Litigation, 653 F. 2d 514, 519 (D.C. Cir. 1981) (en banc), cert. denied, 454 U.S. 822 (1981). The full Court of Appeals' analysis of the federal and state roles in the administration of the Surface Mining Act remains Particularly instructive today:

Under a state program, the state makes decisions applying the national requirements of the Act to the particular local conditions of the state. The Secretary is initially to decide whether the proposed state program is capable of carrying out the provisions of the Act but is not directly involved in local decisionmaking after the program has been approved.

653 F. 2d at 518.

It is with an approved state law and with state regulations consistent with the Secretary's that surface mine operators must comply. See, Act section 502(a), 518(i). Administrative and judicial appeals of permit decisions are matters of state jurisdiction in which the Secretary plays no role. Act section 514.

Once the state has assumed all these functions, the Secretary's role is primarily one of oversight. The statute requires occassional federal on-site inspections to evaluate the administration of the approved state program. Act section 517(a). Interested persons may also report suspected violations . . and if [the Secretary] has reason to believe the allegations he must notify the state regulatory authority. Act section 521(a). If the state fails to take appropriate action the Secretary is to order a federal inspection of the minesite. Id. Violations that threaten imminent environmental harm are to be halted by a cessation order from the Secretary. Act section 521 (a)(2).

The Secretary's ultimate power over lax state enforcement is set out in section 521(b). When the Secretary determines that violations result from a state's lack of intent or capability to enforce the state program, he is to enforce permit conditions directly, and to take over the entire permit-issuing process himself.

* * *

The appeals court's view of the statutory scheme sets forth the enforcement scheme as originally proposed in 1978. 43 FR 41795, 41930. Only under two limited circumstances may the Secretary interve directly: (1) Section 521(a)(2), when a significant imminent harm to the environment or public safety exists; and (2) Sections 504(b) and 521(b), when the state is failing to enforce all or part of its program and the Secretary has given notice to that effect.

More recenlty, several other federal courts have reached an idential construction of the Act. Clinchfield Coal Company v. Hodel, Civ. No. 85-0113-A (W.D.VA. June 20, 1985 and Sept. 25, 1985) appeal docketed, No. 85-2206 (4th Cir. Dec. 13, 1985); United States v. Camp Coal Company, Inc., Civ. No. 85-AR-2117-S (N.D. Ala. Feb. 20, 1986); Drummond Coal Co., Inc. v. Hodel., Civ No. 85-AR-1411-S (N.D. Ala. June 5, 1985). See also, Excello Coal Corp. v. Clark, Civ. No. 3-84-904 (E.D. TN Dec. 27, 1984); Alternate Fuels, Inc. v. OSM, OHA No. TN 5-23-R (July 11, 1985). In Clinchfield, the district court, after an extensive review of the statute and its legislative authority, concluded that OSM's regulation at 30 CFR 843.12(a)(2) "directly conflicts with the intent of Congress" and "significantly expands the authority of OSM beyond that set forth in the Act." Memo Op. at 17-18 (June 20, 1985).

3. The Statute

A textual analysis of the Act discloses the absence of any statutory authority for federal NOVs in the oversight of state programs. The source of inspection and enforcement authority rests with Section 521. Section (a)(1) delineates the circumstances for ordering a federal inspection and the notification requirements where the state is the regulatory authority. Section (a)(2) authorizes OSM to issue immediate cessation orders upon detection of a violation which creates an imminent danger or a significant, imminent environmental harm. This provision explicitly authorizes the issuance of the cessation order "on the basis of any Federal inspection." 30 U.S.C. 1271(a)(2). In sharp contrast stands the statutory provision which authorizes the issuance of NOVs. The statute predicates the use of NOV authority upon only those inspections specifically delineated as follows:

(3) When on the basis of a federal inspection which is carried out during the enforcement of a Federal program, or a Federal lands program. Federal inspection pursuant to section 502, or section 504(b) or during Federal enforcement of a state program in accordance with Subsection (b) of this section . . .

Section 521(a)(3).

This subsection does not convey carte blanche authority similar to section (a)(2). It fails to mention section 517(a) inspections "necessary to evaluate the administration of an approved state program." 30 U.S.C. 1267(a). The only statutory provisions referenced in section 521(a)(3) authorizing federal NOV's in primacy states relates to the formal substitution of enforcement for all or part of a state program pursuant to sections 504(b) and 521(b). The use of this authority only follows after adherence to the rulemaking and hearing requirements found in sections 504 and 521, as fully fleshed out in 30 CFR Parts 733 and 736. In other words, neither sections 504(b) nor 521(b) provide an independent source of federal inspection and enforcement authority as presently contemplated in 30 CFR 843.12(a)(2).

Section 521(b) provides for the sustitution of federal enforcement upon the Secretary's findings after notice and a hearing that: (1) Violations of all or any part of a state program result from the state's failure to enforce the program effectively; and (2) the state has failed to demonstrate its capability and intent to enforce the program. Section 504(b), found in the statutory provision for establishing federal programs, provides OSM with transitional enforcement

authority between the time OSM withdraws state program approval and the final promulgation of a federal program. Section 504(b) is located between the provision authorizing the promulgation of federal programs in states with an existing program, section 504(a)(3), and the provisions which govern the procedure for implementation of a federal program section 504(c)-(f). This construction of section 504(b) and 521(b) has also been the agency's since the inception of the permanent program. See 43 FR 41678 (September 18, 1978) and 44 FR 14969, 15298, 15302 (March 13, 1979).2

OSM's existing regulation at 30 CFR 843.12(a)(2) conflicts wih the canons of statutory interpretation by obscuring Congress' careful draftmanship in delineating the distinct basis for federal imminent danger cessation orders and the notices of violation in states with approved programs. Clearly, Congress would have used the same prefatory language of section 521(a)(2), i.e., "any federal inspection," in section 521(a)(3) if it intended OSM to issue NOVs directly in its oversight role. Accordingly, the Act remains unambiguous in its lack of any statutory provision authorizing the direct issuance of federal NOVs in the oversight of approved state programs.

4. Legislative History

Where statutes are clear, one does not resort to the legislative history to glean statutory intent. Nevertheless, since OSM relied strictly upon "conflicting" statements in the legislative history for promulgating 30 CFR 843.12(a)(2), a contemporary analysis will remove any doubt surrounding the issue. See 44 FR 15302 (March 13, 1979). Contrary to OSM's 1979 characterization of the legislative history as "conflicting," the legislative history appears as clear as the statute in evincing Congress' purposeful distinction for OSM's authority to issue directly an imminent danger cessation order during oversight while not conferring similar powers for notices of violation.

The last House Committee report describes the distinct and broader authority reposed with OSM under section 521(a)(2):

The imminent danger or environmental harm closure provision is so critical that the federal inspector is required to act even if the inspection is being made for purposes of monitoring a state regulatory authority's performance.

H.R. Rep. No. 218, 95 the Cong., 1st Sess. 129 (1977).

Identical passages appear in S. Rep. No. 128, 95th Cong., 1st Sess. 40 (1977); H.R. Rep. No. 1445, 94th Cong. 2d Sess. 77 (1976); and, H.R. Rep. No. 45, 94th Cong., 1st Sess. 119 (1975). In several committee reports the discussion of the enforcement provisions are prefaced with the following remark:

The role of the Federal Government has been carefully delineated in this bill, particularly in regard to its activities in those situations when the state is the prime regulatory authority.

H.R. Rep. No. 896; H.R. No. 45. See also. S. Rep. No. 28 94th Cong. 1st Sess. 181 [1975] (521(a)(2) "is the only place" where federal inspector acts in a state with primacy).

Like the statute itself, the committee reports discussions of section 521(a)(2) which begin with "during any federal inspection," ³ stand in sharp contrast to the descriptions of section 521(a)(3) authority which begin with:

Where the Secretary is the regulatory authority or federal inspection is being conducted pursuant to section 502, 504(b) or section (b) of section 521, . . .

H.R. Rep. No. 218, supra at 130.

Moreover, the last Senate Report removes any doubt as to the scope of federal authority under section 521(a)(3) once the Secretary approves a state program:

In order to prevent federal-state overlap, the federal inspector is only to use his authority under section 421(a)(3) where the Secretary is the regulatory authority. However, in other circumstances the Secretary must insure, in accordance with the provisions of section 421(a)(1), that the state is notified of the compliance problem so that it may act under the terms of the approved state program.

S. Rep. No. 128, 95th Cong. 1st Sess. 90 [1977].4

This same passage appears in the 1975 Senate Committee Report accompanying an earlier version of S. 7. S. Rep. No. 28, 94th Cong. 1st Sess. 182 (1975).

^{*}The agency's adherence to this interpretation of Sections 504(b) and 521(b) remains readily apparent from the text of the enforcement regulation itself. The regulation at issue in this petition, 30 CFR 843.12(a)(2), authorizes federal oversight NOVs in the basis of "any federal inspection other than the one described in paragraph (a)(1) of this section . ." Among the inspections delineated in paragraph (a)(1) are "during federal enforcement of a state program under Section 504(b) or 521(b) of the Act and Part 733 of this chapter . .." Thus, the agency's regulations construe Sections 504(b) and 521(b) inspections as those occurring in conjunction with the formal substitution of federal enforcement of a state program and/or complete or partial withdrawal of state program approval under Part

³ Several House Reports, include the emphasis on the term "any."

⁴ Section 421 of the Senate Bill S.7, was the identical counterpart to section 521 of the law as enacted

Finally, the Conference Report underscores the limited role of the Secretary with respect to the day-to-day enforcement of state programs. While the House and Senate versions contained slightly different procedural elements, both clearly envisioned section 521(b) as the Secretary's exclusive mechanism for direct intervention.

Another issue presented in the enforcement section of the legislation is the differing procedures by which the Secretary can enforce part of a state program. The House receded from its position that the Secretary could exercise this authority upon the finding of a state's failure to enforce, and the conference adopted the Senate amendment's requirement for a public hearing prior to such action by the Secretary.

H.R. Rep. No. 493, 95th Cong. 1st Sess. 110 (1977).

Next to the statute itself, the conference report presents the most persuasive evidence of Congressional intent since it contains the final statement of terms agreed to by both houses. National Assn'n. of Greeting Card Publishers v. United States Postal Service, 462 U.S. 810, 832 N. 28 (1983); Demby v. Schweikee, 671 F. 2d 507, 510 (D.C. Cir. 1981).

The Act's legislative history supports a statutory construction that OSM has no authority to issue directly notices of violation in its oversight of the state's administration of their approved programs absent the agency initiating formal administrative action pursuant to sections 504(b), 521(b) of the Act and Part 733 of the agency's regulation. Contrary to OSM's conclusions in 1979 that Congress left a statutory "void," the legislative history discloses that the absence of direct NOV authority under the permanent program was clearly intended by both houses.

5. Available Oversight Procedures

A review of the manner in which OSM has employed the NOV as an oversight tool discloses that instead of filling some perceived statutory "void," the agency has created for itself a regulatory loophole to circumvent established procedures for resolving oversight problems with the states. The original reason used by OSM for inserting NOV authority to fill the so-called "gap" was its anticipation that states would ignore violations of the law. However, the typical federal NOV today arises from OSM's disagreement with the state's interpretation of their program, the manner in which the state compels abatement of violations, alleged discrepancies in state issued permits and even deficiencies in state programs approved by OSM. In each instance, the

statute and regulations establish procedures for an "appropriate" OSM response to resolve the matter: program amendments, 30 CFR Part 732, permit revisions, 30 CFR Part 774, and preemption of state law, 30 CFR Part 730.

OSM's strict reliance upon the NOV sanction to address ovesight problems has led to a perverse policy scheme. The agency overreacts in the "gray" areas of the law and fails to act decisively in the "black and white" situations. The agency wastes its resources in battle over the nuances of state programs, and simultaneously ignores the occurrences of alleged program-wide departures. For example, where it has been reported that a state issued almost 2,000 allegedly illegal two-acre permits, OSM responded by addressing some of the symptoms of the problem with a handful of "oversight" NOVs, rather than focusing upon the cause of the problem through a Part 733 investigation. Whether or not the state did or did not act properly under its state law for regulating two-acre operations remains unresolved. Such an approach leaves a cloud of unsubstantiated allegations over the continued operation of an approved state program and denies public access to the process for considering changes to the approved program.

The disparities evolving from this "symptomatic" oversight policy become increasingly clear. Operators faithfully following the state's interpretation of an approved performance standard with which OSM disagrees, find themselves subject to more onerous sanctions than those attempting to operate outside the reach of the law. We suspect that an environmental analysis of OSM's "symptomatic" oversight policy would disclose that significant environmental impacts result from OSM's complacent use of oversight NOVs to address both the acknowledged widespread abuse, and the legitimate interpretational disputes. Each circumstance mandates a more appropriate response than oversight NOVs. Widespread abuse evolving from the breakdown of a state program deserves a section 521(b) hearing. Interpretation disputes require comprehensive resolution through the program amendment process.

OSM's reflexive use of oversight NOV's to address the states' implementation of their programs has rendered the full range of oversight tools superfluous. Again, from a policy perspective, the resolution of program deficiencies, interpretation disputes and permit discrepancies is better suited for the established procedures for program amendments and permit revisions. To

the extent a state response to a ten-daynotice discloses a view of a program or permit requirement different than that shared by OSM, the program amendment or permit revision processes reach the issue at a broader programlevel. Moreover, the underlying issues in controversy between OSM and the state, deserve meaningful consideration through a rulemaking proceeding with broader public participation than that which occurs in an isolated enforcement proceeding. Finally, inasmuch as the permittee appears to follow policies or practices approved by the state, and thus, OSM's dispute rests with the state, the focus of the resolution process should also remain upon the state.

(a) Program Amendment Process. OSM regulations delineate three circumstances which may dictate the need for a state program amendment: (1) Changes in the Act or federal regulations; (2) conditions or events which change the implementation or enforcement of the state program; and (3) conditions or events which indicate that the approved program no longer meets the requirements of the Act or federal regulations 30 CFR 732.17(e). The Director notifies a state when he determines an amendment is required, and the state submits a proposed amendment or description with a timetable for enactment under applicable state administrative or legislative procedures. Id. at 732.17(f). The Secretary may invoke section 521(b) to substitute federal enforcement or withdraw program approval for failure to submit amendments 30 CFR 732.17(f).

Deficiencies in an approved state program identified by USA clearly fall within the regulatory framework for soliciting a program amendment. Compliance is measured against the approved state program In Re: Permanent Surface Mining Regulation Litigation, 653 F. 2d at 519. Thus, until OSM and the state complete the amendment process, NOVs remain inappropriate for noncompliance with standards which do not appear in the existing program. Disputes over interpretation of program provisions also fall within the program amendment process. A state response to a ten-day notice demonstrating a program interpretation OSM deems as not meeting the requirements of the Act or federal regulations constitutes an "event" which indicates the possible need for a program amendment 30 CFR 732.17(e)(3). It also remains inappropriate to subject permittees to enforcement sanctions where they have relied upon the state's interpretation of their program. Compliance orders must

only follow after the issue has been resolved through a program amendment procedure and permittees have been afforded a reasonable time to conform ongoing operations. Cf 30 U.S.C. 1271(b).⁵

(b) Permit Revision Process. While an approved state program implements the federal Act in a state, a permit applies program provisions specifically to a mine site with its varying conditions. Permitting under a permanent state program rests exclusively with the state regulatory authority. Both the extensive application requirements and public participation which accompany the permitting process foster the operator's reliance upon the permit as the benchmark for compliance. The Surface Mining Act provides for the periodic review of outstanding permits and the regulatory authority may require reasonable revisions during the permit term. 30 U.S.C. 1261(c). However, written findings accompany any requested revision along with adherence to the notice and hearing requirements established in the state program. Id.

Despite the states' independent role, and available procedures for permit revisions, OSM issues notices of violation for deficiencies it detects in state permits. OSM's permanent program regulations provide the exclusive mechanism for procuring permit revisions. The regulations state explicitly that neither at mid-term review or, "at any time, the regulatory authority may, by order, require reasonable revision of a permit . . . to insure compliance with the Act and the regulatory program." 30 CFR 774.11(b). The regulatory authority's order is not a notice of violation, but the order prescribed in section 511(c), 30 U.S.C. 1261(c). OSM's use of notices of violation where it detects a permitting deficiency contravenes the statute and regulations.6

⁵ We note the availability of section 505 preemption authority for state laws the Secretary determines to be inconsistent wit the federal Act. OSM rarely invokes its preemption authority, yet it appears as a viable mechanism to address emergency situations. See eg. 50 FR 42727 [Nov. 20, 1985]; 50 FR 35082 (Aug. 29, 1985). Both the Act and regulations require OSM to follow formal rulemaking procedures. 30 U.S.C. 1255(b); 30 CFR 730.11. Like the program amendment process, section 505 procedures resolve the underlying issue on a program-wide basis and places everyone on notice as to accepted interpretations of the law.

Like program deficiencies, the federal statute and regulations set forth an orderly process, short of an enforcement action, for resolving deficiencies identified in existing permits. The process involves notice and an opportunity for a hearing to resolve disagreements over permit requirements which arise during the permit term. OSM preference for invoking direct enforcement sanctions through NOVs amounts to nothing short of a violation of the federal statute and regulations.

(c) Section 521(b) Notice and Hearings. The substitution of federal enforcement for any part of a state program or promulgation of a federal program remain OSM's ultimate power over lax state enforcement. 30 U.S.C. 1271(b); See also, In Re: Permanent Surface Mining Regulation Litigation (en banc), 653 F. 2d at 520; Clinchfield Coal Company v. Hodel, Memo Op. at 2. The statute sets forth a two-tiered test for substituting federal enforcement or withdrawing program approval: (1) Violations exist from the failure of the state to enforce all or any part of its program effectively and (2) the state has not adequately demonstrated its capability and intent to enforce its program. 30 U.S.C. 1271(b). See also, 30 CFR 733.12(e).

While the actual substitution of federal enforcement or federal program is clearly intended as a last resort measure, the initiation of such proceedings as an oversight tool to address widespread enforcement disparities has been ignored by OSM. Nothing mandates that OSM withdraw approval or substitute enforcement after it has decided to hold a hearing pursuant to section 521(b). In fact, the implementing regulations, 30 CFR Part 733, afford ample opportunity to resolve the issues with the state short of substituting either federal enforcement or a federal program. For example, the regulations require that OSM provide the state with notice and time to respond to allegations. The state may also request a conference to resolve the dispute. If the problem persists, then OSM holds a public hearing to gather further information and comments. The results of the hearing and investigation

private operator. The Senate Conference Report explained that the distinction in "Subsection (a) assures that no operator can be sued under this section if he is operating in compliance with all regulations, orders and an approved permit, even though the regulating authority . . . has failed to properly implement the Act." S. Rep. No. 101, 94th Cong. 1st Sess. 84 (1975). See also, 121 Cong. Rec. S6176 (daily ed. March 12, 1975).

formulate the basis of the Director's findings that the state has corrected the problem, or that the state has not demonstrated the capability and intent to do so. Only if OSM makes the latter finding do the sanctions of substituted federal enforcement and/or withdrawal of program approval follow.

As a general matter, Petitioners have no quarrel with the circumspect use of substituting federal enforcement or withdrawal of program approval.

Nevertheless, we find the agency's "all or nothing" approach to Part 733 proceedings as perpetuating the uncertainty which historically plagues the program. Employment of limited Part 733 proceedings as an oversight tool to resolve comprehensive problems with program implementation, in a public forum, will likely yield more rational and decisive results than direct federal enforcement sanctions.

The issues underlying disputes over proper program implementation deserve more meaningful consideration than that which occurs through isolated enforcement sanctions against operators relying upon the states' representations as to the meaning of the applicable law. If OSM's position is ultimately correct, then it should withstand the scrutiny of review in a public forum. More importantly, the issues will be resolved in an comprehensive fashion as opposed to the piecemeal approach which occurs through oversight notices of violation.

D. Standard of Review for Appropriate Action by the State

Even without the authority to directly issue NOVs in states with approved programs, the evaluation of state responses to ten-day-notices for "appropriate action" under section 521(a)(1) remains an integral function in OSM's oversight. First, the State's failure to take appropriate action is a condition precedent to the issuance of federal imminent danger cessation orders. 30 U.S.C. 1271(a)(1); 30 CFR 842.11(b)(1); See also, Donald St. Clair et. al, 77 1BLA 283, 306 (1983). Second, the evaluation of state responses to tenday notices will assist OSM's evaluation of state programs under 30 CFR 733.12(a)(1). See also, 44 FR 15302 (March 13, 1979).

The absence of an established standard of review for OSM's evaluation has led to considerable disparity in the treatment of coal operators and the states. Numerous instances of direct federal intervention demonstrate a pattern of mere substitution of an OSM inspector's

⁶ A distinction in section 520(a) of the Act's citizen suit provision also evinces Congress' intent that operators not become unwitting victims of errors which may occur during the permitting process. 30 U.S.C. 1270(a). While public agencies, e.g., TVA, conducting surface coal mining operations are subject to a citizen suit for violations of the Act, the same action does not lie against a

subjective judgment for that of the state regulatory authority. This practice clearly contravenes both the intent and purpose Congress expressed in the statute. 30 U.S.C. 1201(f); 1211(c)(9). Moreover, it subjects the states' policy decisions to a higher level of scrutiny than that set forth for the Secretary under the Surface Mining Act, 30 U.S.C. 1276(a)(1), and the Administrative Procedure Act, 5 U.S.C. 706(2)(A).

Administrative agencies traditionally have been afforded broad discretion in the interpretation and enforcement of their regulatory programs. Heckler v. Chaney, 105 S. Ct. 1649, 1655 (1985). National Wildlife Federation v. Gorsuch, 693 F. 2d 156, 167, 171 (D.C. Cir. 1982); City of Seabrook v. Costle, 659 F. 2d 1371, 1374 (5th Cir. 1981). The same deference accorded the Secretary by the judiciary applies equaly to the states in the Secretary's oversight of the states' administration of their programs. In Re: Permanent Surface Mining Regulations Litigation, 653 F. 2d. 514 (D.C. Cir. 1981) (en banc). In its review of OSM's statutory oversight role, the full Court of Appeals concluded that "[o]nce a state program has been approved, the state agency plays the major role, with its greater manpower and familiarity with local conditions. It exercises front-line supervision and the Secretary will not intervene unless its discretion is abused." Id. at 523 (emphasis added). Accord, Clinchfield Coal Company v. Hodel, No. 85-0113-A (W.D. Va. June 20, 1985); Drummond Coal Company Inc. v. Hodel, No. 85-AR-1411-S (N.D. Ala. June 5, 1985).

The very language of section 521(a)(1) ("appropriate action" or "show good cause") connotes the discretionary nature of the state action. Accordingly, in reviewing responses to ten-daynotices which allege that a condition or practice possibly constitutes a violation. OSM must determine whether the state's decision was within the bounds of discretion provided by the state program and other applicable law. In the performance of this evaluation, OSM should carefully consider whether the state decision was within the permissible range of choices considering all relevant factors as to not be arbitrary, capricious and an abuse of discretion. Absent promulgation of the standard of review requested by Petitioners, OSM will remain a duplicative regulatory body.

V. Conclusion

The requested amendments and modifications to OSM's Federal inspection and enforcement regulations will conform the permanent regulatory program to the plain language of the

statute, congressional intent and existing case law. Moreover, the changes, as requested, will correct severe flaws in OSM's present approach to oversight by directing the agency's monitoring efforts to the appropriate procedures already established for resolving the issues which arise in the course of the states' implementation of their approved regulatory programs.

Accordingly, for the reasons stated herein, Petitioners request that the Director immediately grant the petition pursuant to section 201(g) of the Surface Mining Act, 30 U.S.C. 1211(g), and 30 CFR 700.12, and promptly thereafter commence an appropriate proceeding to promulgate the requested amendments and modifications in accordance with section 501 of the Surface Mining Act, 30 U.S.C. 1251, and 5 U.S.C. 553.

Respectfully submitted.

Mining and Reclamation Council of America. 1575 Eye Street, NW., Suite 525, Washington, DC 20005

By:

Harold P. Quinn, Jr.,

Director, Government Affairs.

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[FR Doc. 86–17055 Filed 7–29–86; 8:45 am]
BILLING CODE 4310–05-M

30 CFR Part 935

Ohio Permanent Regulatory Program; Reopening and Extension of Public Comment Period on Proposed Amendments

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Reopening and extending the public comment period.

SUMMARY: By letter dated March 3, 1986, the Ohio Department of Natural Resources (ODNR) submitted proposed amendments to Ohio's regulatory program at 1501:13–4–05; 1501:13–14, and 1501–13–9–07. The proposed changes to Ohio Administrative Code (OAC) 1501:13–4–05, and 1501:13–4–14, set forth the permitting requirements for surface and underground mining operations, respectively, with regard to rock-toe buttresses and key-way cuts.

OAC 1501:13-9-07 is a completely new regulation concerning the disposal of excess spoil. The proposed amendment was necessary to address deficiencies identified in the Ohio program regarding the disposal of excess spoil.

OSMRE published a notice in the Federal Register on April 4, 1986, announcing receipt of the amendment and inviting public comment on the adequacy of the proposed amendment (51 FR 11588).

Following a review of the Ohio amendments, OSMRE notified the State on May 21, 1986, of its concerns about the proposed amendment to OAC 1501:13-9-07. These concerns relate to the design of fills and appurtenant structures by registered professional engineers with experience in the design of rock and earth fills; requiring sufficient foundation investigation and laboratory testing of foundation materials; requiring the storage or redistribution of topsoil removed from the disposal site and the stabilizing of all surface areas immediately following completion of construction; design and contruction standards for underdrains and diversions in the disposal area, and the need for color photographs showing the stages of underdrain construction.

In June 23, 1986, the ODNR responded by submitting a revision of the amendment to address OSMRE's concerns. The revisions to OAC 1501:13– 907 also include a revised definition of "engineer" and moves the definition of "durable rock" from paragraph (B) to (H) (3), (M) (2) (a) and (N) (2).

Accordingly, OSMRE is reopening and extending the comment period on Ohio's

March 3, 1986 amendment as modified on June 23, 1986. The action is being taken to provide the public with an opportunity to reconsider the adequacy of the proposed amendments.

DATE: Written comments, data or other relevant information relating to this rulemaking not received on or before 4:00 pm August 14, 1986, will not necessarily be considered in the Director's decision to approve or disapprove the amendment.

ADDRESS: Written comments should be mailed or hand delivered to: Ms. Nina Rose Hatfield, Director, Columbus Field Office, Office of Surface Mining Reclamation and Enforcement, Room 202, 2242 South Hamilton Road, Columbus, Ohio 43227. Telephone: (614) 866–0578.

Copies of the Ohio program, the proposed modification to the program and all written comments received in response to this notice will be available for public review at the OSMRE Field Office listed above and at the OSMRE Headquarters Office and the Office of the State regulatory listed below during normal business hours Monday through Friday, excluding holidays. Each requestor may receive, free of charge, one single copy of the amendment by contacting the OSMRE Columbus Field Office listed above.

Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 5315A, 1100 "L" Street NW., Washington, DC 20240.

Ohio Division of Reclamation, Building B, Fountain Square, Columbus, Ohio 43224.

FOR FURTHER INFORMATION CONTACT: Ms. Nina Rose Hatfield, Director, Columbus Field Office, Office of Surface Mining Reclamation and Enforcement, Room 202, 2242 South Hamilton Road, Columbus, Ohio 43227. Telephone: (614) 866–0578.

SUPPLEMENTARY INFORMATION:

I. Background

The Ohio program was conditionally approved effective August 16, 1982, by notice published in the August 10, 1982 Federal Register (47 FR 34688). Information pertinent to the general background, revisions, modifications, and amendments to the Ohio program submission, as well as the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Ohio program can be found in the August 10, 1982 Federal Register. Subsequent actions concerning the Ohio program conditions of approval and program amendments can be found 30 CFR 935.11 and 935.15.

II. Proposed Amendments

By letter dated March 3, 1986, the Ohio Department of Natural Resources, Division of Reclamation submitted amendments to Ohio's regulatory program at 1501:13–4–05, 1501:13–9–07. The proposed changes to OAC 1501:13–4–05, and 1501:13–4–14, set forth the permitting requirements for surface and underground mining operations with regard to rock-toe buttresses and keyway cuts. OAC 1501:13–9–07 is a completely new regulation concerning the disposal of excess spoil.

During review of amendments OSMRE identified several concerns relating to the disposal of excess spoil regulation, OAC 1501:13-9-07. This concerns included requiring the design of fills and appurtenant structures to be by registered professional engineers with experience in earth and rock fills: requiring sufficient foundation investigations and laboratory testing of foundation materials; requiring the storage or redistribution of topsoil removed from the disposal site and the stabilizing of all surface areas immediately following completion of construction; the design and construction standards for underdrains and diversions in the disposal area, and the need for color photographs showing the stages of underdrain construction. OSMRE notified the State of these concerns by letter dated May 21, 1986.

On June 23, 1986, the ODNR responded by submitting revisions to OAC 1501:13-9-07 that address OSMRE's concerns. The revisions to OAC 1501:13-9-07 also include a revised definition of "engineer" and moves the definition of "durable rock" from paragraph (B) to (H)(3), (M)(2)(a), and (N)(2). The revised proposed rules are designed to ensure that the disposal of excess spoil will not adversely effect surface or ground water, cause erosion or threaten public health or safety.

The full text of the June 23, 1986 revised amendment is available for review at the locations listed above under "ADDRESSES". OSMRE is now seeking comment on the March 3, 1986 amendment as revised on June 23, 1986. If the Director determines that the proposed amendment is no less stringent than SMCRA and no less effective than the Federal regulations, the amendment will be approved and become part of the approved permanent program.

List of Subjects in 30 CFR Part 935

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: July 23, 1986.

Brent Walquist,

Assistant Director, Program Operations.

[FR Doc. 86–17056 Filed 7–29–86; 8:45 am]

BILLING CODE 4310–05-M

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. 60594-6094]

Rules for Extension of Patent Term

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Patent and Trademark Office proposes to amend the rules of practice in patent cases, Part 1 of Title 37, Code of Federal Regulations, to provide the rules and procedures under which extensions in the terms of patents may be sought pursuant to the provisions of 35 U.S.C. 156 which was enacted on September 24, 1984 in Title II of Pub. L. 98-417, the "Drug Price Competition and Patent Term Restoration Act of 1984." The new 35 U.S.C. 156 provides that, upon application to the Commissioner of Patents and Trademarks, the term of a particular patent, which claims a product or a method of using or manufacturing a product as defined in the Public Law, may be extended under certain circumstances and conditions where the product has been subject to a regulatory review as defined in Public Law 98-417 and by the Secretary of Health and Human Services, before its commercial marketing or use. The proposed rules for amending Part 1 of Title 37 would provide specific procedures for the submission of such applications to the Patent and Trademark Office and for the determination and issuance of certificates of patent term extension by the Patent and Trademark Office on the applications submitted.

DATES: Comments must be submitted on or before September 10, 1986; a public hearing will be held on September 15, 1986 at 9:30 a.m., requests to present oral testimony should be received on or before September 10, 1986.

ADDRESS: Address written comments and requests to present oral testimony to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, Attention: Charles E. Van Horn, Room CP2-9A09. The hearing will be held in Room 11C10, on the 11th floor of Building 3, Crystal Plaza, located at 2021 Jefferson Davis Highway, Arlington, Virginia. Written comments and a transcript of the public hearing will be available for public inspection in Room 9A09 of Building 2, Crystal Plaza at 2011 Jefferson Davis Highway, Arlington, Virginia.

Charles E. Van Horn by telephone at (703) 557–3637 or by mail marked to his attention and addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

SUPPLEMENTARY INFORMATION: These proposed rules are designed primarily to implement Title II of Pub. L. 98–417 by (1) establishing the rules and procedures for the submission of applications for the extension of patent term to the Patent and Trademark Office and (2) by defining the procedures governing the extension determination and issuance of certificates of patent term extension by the Patent and Trademark Office based on the applications submitted.

Since new section 35 U.S.C. 156 came into effect on the date of enactment (September 24, 1984) of Public Law 98-417, initial operating guidelines were published as "Guidelines For Extension of Patent Term Under 35 U.S.C. 156" in the Official Gazette of the Patent and Trademark Office on October 9, 1984. The guidelines were also published in BNA's Patent, Trademark and Copyright Journal on September 27, 1984. It is intended that those guidelines will continue in effect until the promulgation of final rules based on the proposed rulemaking. These proposed rules follow in most respects the practice and procedures set out in the guidelines but the proposed rules make some clarifications and additions to the guidelines. For example, proposed new §§ 1.775, 1.776, and 1.777 set out how the period of patent term extension is to be calculated, which was not covered in the guidelines.

The new section 35 U.S.C. 156 requires the Commissioner of Patents and Trademarks to notify the Secretary of Health and Human Services within sixty days of the submittal of an application for extension of patent term which complies with the section and to submit to the Secretary a copy of the application. Not later than thirty days after receipt of the application from the Commissioner, the Secretary is charged with determining the length of the applicable regulatory review period. notifying the Commissioner of the determination and publishing in the Federal Register a notice of such determination.

The Secretary of Health and Human Services is responsible for publishing regulations to give guidance concerning the handling of applications for patent term extension in the Department of Health and Human Services.

Discussion of Specific Rules

Section 1.1, if amended as proposed, would indicate that applications for extension of patent terms and any communications relating thereto intended for the Patent and Trademark Office should be directed to "Box Patent Ext."

The filing of an application for an extension of the term of a patent would be considered timely if received in the Patent and Trademark Office on or before the statutory deadline, or if the application is deposited with the U.S. Postal Service in accordance with the provisions of § 1.8 or § 1.10 of this part before the statutory deadline. The filing of an application for an extension of the term of a patent would be treated in the same manner as the filing of any paper required to be filed in the Patent and Trademark Office within a set period of time and not subject to the exceptions enumerated in 37 CFR 1.8(a). Section 1.20, if amended a proposed,

Section 1.20, if amended a proposed, would add paragraph (n) to establish a fee of \$550.00 for filing an application for extension of the term of a patent pursuant to \$1.740. This amount is appropriate to cover the costs to the Patent and Trademark Office of receiving and acting upon applications for extension of patent term as provided in 35 U.S.C. 156(h).

A new "Subpart F—Extension of Patent Term" is proposed to be added to Part 1 to include §§ 1.710 through 1.785.

Section 1.710, if added as proposed. would define the patents subject to extension of the patent term. Paragraph (a) of proposed § 1.710 defines the patents subject to extension in terms of the subject matter being claimed therein. Under paragraph (a) of proposed § 1.710 a patent to (1) a product, (2) a method of using a product, (3) or a method of manufacturing a product can be extended as long as the product meets the definition contained in paragraph (b) of proposed § 1.710, and as long as the other conditions and requirements for extension of patent term are met. Paragraph (b) of proposed § 1.710 follows the language of 35 U.S.C. 156 and defines a "product" as meaning (1) a human drug product or (2) any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act, The term "human drug product" as defined in paragraph (b) of proposed § 1.710 means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the

Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

Section 1.720, if added as proposed, would define the conditions under which the term of a patent may be extended. The conditions for extension would be:

(1) The patent must claim a product or a method of using or manufacturing a product as defined in proposed § 1.710;

(2) The term of the patent must never have been previously extended except for any interim extension issued pursuant to § 1.760;

(3) An application for extension must be submitted pursuant to proposed § 1.740:

(4) The product must have been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use;

(5) The product must have received permission for commercial marketing or use and (i) the application must be submitted within the sixty day period beginning on the date the product first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred, or (ii) in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension must be submitted within the sixty day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent;

(6) The term of the patent must not have expired before the submission of an application pursuant to proposed § 1.740; and

(7) No other patent must have been extended for the same regulatory review period for the product.

Section 1.730, if added as proposed. would require that an application for extension of a patent be submitted by the owner of record of the patent or its agent and that the application must comply with the requirements of proposed § 1.740. The application papers submitted would be required to clearly reflect and establish the authority of the person submitting the application to do so on behalf of the owner. See proposed § 1.740(c). For example, if the person submitting the application is the owner of record, the application papers would be required to so reflect. If the person submitting the application is doing so as the agent of the owner of record, the

application papers must so reflect and establish the authority of the agent to act on behalf of the owner, e.g., as an officer of a corporate owner. A mere power of attorney to prosecute a patent application before the Patent and Trademark Office would not establish the agency relationship to apply for a patent term extension.

Section 1.740, if added as proposed, would establish the contents and requirements of an application for extension of patent term. Paragraph (a) of proposed § 1.740 requires that the application be made in writing to the Commissioner of Patents and Trademarks and establishes as the filing date of the application the date on which the complete application for extension as defined in paragraph (b) of the section and a duplicate of the papers thereof, certified as such, are received in the Patent and Trademark Office or filed pursuant to the "Certificate of Mailing" provisions of 37 CFR 1.8 or by "Express Mail" pursuant to the provisions of § 1.10. The certified duplicate of the application papers will serve as the copy to be submitted by the Commissioner to the Secretary of Health and Human Services in order that the Secretary may determine the applicable regulatory review period as required by Pub. L. 98-417.

Paragraph (b) of proposed § 1.740 specifies the contents of a complete application for extension of patent. The complete application, and a certified duplicate thereof, must be submitted in order that a filing date for the application can be established. If the application is not complete when submitted it will be refused a filing date until such time as the omission is corrected. In accordance with paragraph (b) of proposed § 1.740, a complete application for the extension of the term of a patent comprises:

(1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics that would permit the Commissioner to make a determination of whether the patent claims the approved product, or a method of making or using the approved product;

(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred;

(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred:

(4) In the case of a human drug product, an identification of each active ingredient in the product and as to the product and each active ingredient, a statement that they have not been previously approved for commercial marketing or use under the Federal Food Drug and Cosmetic Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients) and the provision of law under which it was approved.

(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to proposed § 1.720 (e) and an identification of the date of the last day on which the application could be submitted:

(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, and the date of issue;

(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings;

(8) A copy of any disclaimer, certificate of correction, receipt or statement of maintenance fee payment, or reexamination certificate issued in the patent;

(9) A statement beginning on a new page that the patent claims the approved product or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which each applicable patent claim reads on the approved product or a method of using or manufacturing the approved product;

(10) A statement beginning on a new page of the relevant dates and information pursuant to 35 U.S.C. 156 (g) in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review period.

(i) For a human drug product, this information will include the effective date of the investigational new drug (IND) application and the IND number; the date on which a new drug application (NDA) was initially submitted and the NDA number; and the date on which the NDA was approved;

(ii) For a food or color additive, this information will include the date a major health or environmental effects test on the additive was initiated and any available substantiation of that date; the date on which a petition for product approval under the Federal Food, Drug and Cosmetic Act was initially submitted and the petition number; and the date on which the application was approved;

(iii) For a medical device, this information will include the effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device if no IDE was submitted and any available substantiation of that date; the date on which an application for product approval under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted and the number of the application; and the date on which the application was approved.

In the cases where there is no regulatory event to reflect the commencement of the testing or approval phase of the regulatory review period, applicants should include in applications the dates that they claim initiate either the approval or the testing phases and an explanation of their reasonable basis for why they conclude that these dates are the relevant dates. For instance, when the clinical trials are conducted outside the United States, the testing phase for a medical device begins on the date the clinical investigation involving the device was begun. An applicant should include an explanation as to why the date claimed is the date on which such clinical investigations had commenced. If the applicant had any means of substantiating that date, that information should be included in the application.

Finally, on this separate page in the application there should be a statement as to the length of the regulatory review period claimed including an explanation of how the applicant determined the length of the regulatory review period. It should be noted in the application that this particular calculation is made solely with respect to section 156(G)(1) thru (3) of Title 35 of the United States Code and does not take into account any other limitations or restrictions on the length of possible patent extension.

(11) A brief description beginning on a new page of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities. This description should include a summary of any communication of substance with the Food and Drug Administration (FDA) and the significant dates related to such communication and activities. For example, these activities would include the dates of the submission of any new data to the FDA, any communications between FDA and the applicant with respect to the appropriate protocols for testing the product, and

any communications between FDA and the applicant that are attempts to define the particular requirements for premarketing approval of this particular

product.

(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined and whether the 14 year limit of 35 U.S.C. 156(c)(3), the five year limit of 35 U.S.C. 156(g)(4)(A) or (B) or the two year limit of 35 U.S.C. 156(g)(4)(C) applies.

(13) A statement that applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought (see

§ 1.765):

(14) The prescribed fee for receiving and acting upon the application for

extension (see § 1.20(n));

(15) The name, address, and telephone number of the person to whom contacts and correspondence relating to the application for patent term extension are to be directed; and

(16) An oath or declaration as set forth in paragraph (c) of proposed

§1.740.

Paragraph (c) of proposed § 1.740 requires that an oath or declaration signed by the owner of record of the patent or its agent accompany the application as a part thereof. An application for extension filed without an oath or declaration is not a complete application and is not entitled to a filing date. The oath or declaration filed as a part of the application must specifically identify the application papers and the patent for which an extension is sought and include averments that the person signing the oath or declaration:

(1) Is the owner, an official of a corporate owner authorized to obligate the corporation, or has specific written authorization to sign the oath or declaration on behalf of the owner;

(2) Has reviewed and understands the contents of the application being submitted pursuant to § 1.740;

(3) Believes the patent is subject to extension pursuant to § 1.710;

(4) Believes an extension of the length claimed is fully justified under 35 U.S.C. 156 and the applicable regulations; and

(5) Believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in § 1.720.

In signing the oath or declaration referred to in paragraph (c) of proposed § 1.740 an official of a corporate owner or a person having specific written authorization to sign the oath or declaration on behalf of the owner is representing that he or she is the agent of the owner and has authority to act on behalf of the owner in filing the application for patent term extension. Note also proposed § 1.730.

Paragraph (d) of proposed §1.740 provides for review of a holding that an application for patent term extension is incomplete by the filing of a petition under 37 CFR 1.182. The failure to timely comply with any requirement of these regulations which is not an explicit requirement of the statute may be waived under appropriate circumstances. 37 CFR 1.183. While timely action is expected, relief under 37 CFR 1.183 may be appropriate in view of the tight time deadlines and other circumstances involved in filing an application for extension of the patent term. The petition must be filed with the required fee (37 CFR 1.17(h)) within such time as may be set, or if no time is set, within one month of the holding.

Section 1.750, if added as proposed, would cover the determination of eligibility for extension of the term of a patent which will be made by the Patent and Trademark Office on the application for extension. As provided for by Pub. L. 98-417, and as set forth in this section, it is intended that the determination as to whether a patent is eligible for an extension can be made solely on the representations contained in the application for extension filed pursuant to proposed new \$1.740 of this part. Proposed § 1.750 does, however, provide that further information may be required by the Commissioner or other officials before a final determination is made on whether a patent is eligible for extension. In circumstances where further information is required by the Office the applicant will be given a time period within which to respond. The failure to file a response within the period provided will result in a final determination adverse to the granting of an extension of patent term unless the response period is extended. An extension of time to respond may be requested under the provisions of 37 CFR 1.136(b). The intentional failure to provide the information requested also will result in a final adverse determination. A final determination may be made at any time after an application is filed, but no later than when a certificate of extension is issued. Proposed § 1.750 provides that a single request for reconsideration of a final determination may be filed within one month or within such other time period set in the final determination. Proposed § 1.750 also provides that the determination may be delegated to

appropriate Patent and Trademark
Office officials. A notice will be mailed
to applicant containing the
determination as to eligibility of the
patent for extension and the period of
time of the extension of the term, if any.
This notice shall constitute the final
determination as to eligibility and any
period of extension of the patent term.

Section 1.760, if added as proposed, would provide for one or more interim extensions for periods of up to one year where a complete application pursuant to proposed § 1.740 has been filed by an applicant and a final determination pursuant to proposed § 1.750 has not been made on the application. Proposed § 1.760 provides that the Commissioner may issue an interim extension with or without a request by the applicant. In order for an interim extension to be granted the application pursuant to proposed § 1.740 must have been filed prior to the expiration date of the patent even though the interim extensions may not actually be granted until after the original expiration date of the patent. In no event will interim extensions be granted under proposed § 1.760 for a period of extension longer than that to which the applicant would be eligible.

Section 1.765, if added as proposed, would define the duty of disclosure in patent term extension proceedings. Paragraph (a) of propossed § 1.765 specifies the individuals on whom the duty rests and the extent of the duty. Paragraph (b) of proposed § 1.765 requires that disclosures pursuant to the section be accompanied by a copy of each written document being disclosed and specifies to whom the submission is to be made, i.e., the Patent and Trademark Office or the Secretary, as appropriate. Such disclosures would be able to be made through and attorney or agent.

Paragraph (c) of proposed § 1.765 precludes a determination of eligibility for an extension or the issuance of a certificate if clear and convincing evidence of fraud or attempted fraud on the Office or the Secretary is determined to be present or the duty of disclosure is determined to have been violated through bad faith or gross negligence in connection with the patent term extension proceeding. Since the determination as to whether a patent is eligible for extension pursuant to proposed § 1.750 may be made solely on the basis of the representations made in the application for extension, a final determination to refuse a patent term extension because of fraud or a violation of the duty of disclosure is expected to be rare.

Paragraph (d) of proposed § 1.765 precludes submissions to the Patent and Trademark Office by or on behalf of third parties, thereby making patent term extension proceedings in the Office an ex parte matter between the patent owner or its agent and the Commissioner. Under paragraph (d) of proposed § 1.765, submissions by third parties to the Office will be returned, or otherwise disposed of, without consideration.

Paragraph (d) does not affect submissions authorized by Public Law 98-417 to be made to the Secretary during determination of the applicable

regulatory review period.

Section 1.770, if added as proposed, would provide for the express withdrawal of an application for extension of the term of a patent if the written declaration of withdrawal signed by the owner of record or its agent is filed in the Office, in duplicate, before a determination is made pursuant to proposed § 1.750. Under proposed § 1.770, and application for extension of the term of a patent may not be expressly withdrawn after the date of the final determination pursuant to proposed § 1.750. Proposed § 1.770 also provides that an express withdrawal is effective when acknowledged in writing by the Office and that the filing and acceptance of an express withdrawal does not entitle applicant to a refund of the filing fee for the application for patent term extension or any portion thereof.

Section 1.775, if added as proposed, would provide the procedure for calculating the patent term extension for

a human drug product.

Proposed paragraph (a) would specify that the extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer.

Proposed paragraph (b) of § 1.775 would provide that the patent term would be extended by the length of the regulatory review period for the product as determined by the Secretary of Health and Human Services but reduced, where appropriate, by the time periods provided in proposed paragraph (d).

Proposed paragraph (c) defines the length of the regulatory review period which is determined by the Secretary of Health and Human Services.

For a human drug product, the regulatory review period is defined in 35 U.S.C. 156(g)(1)(B) as the sum of:

(1) The number of days in the period beginning on the date an exemption under section 505 or 507 of the Federal Food, Drug, and Cosmetics Act became effective for the approved human drug product and ending on the date an application was initially submitted for the drug product under section 505 or 507 above or under section 351 of the Public Health Service Act; and

(2) The number of days in the period beginning on the date the application was initially submitted for the approved human drug product under section 351 of the Public Health Service Act or subsection (b) of section 505 or 507 of the Federal Food, Drug, and Cosmetic Act and ending on the date the application was approved under the section.

This period is then reduced, where appropriate, by the time periods described in proposed paragraph (d).

Paragraph (d) of proposed § 1.775, would define the term of the patent extension by indicating that

(1) The time period determined from proposed paragraph (c) would be reduced, where appropriate by

(i) The number of days in the periods of proposed paragraph (c)(1) and (c)(2) of § 1.775 which were on and before the date on which the patent issued

(ii) The number of days from paragraphs (c)(1) and (c)(2) of § 1.775 during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence; and

(iii) One-half the number of days remaining in the period defined by proposed paragraph (c)(1) after the period has been reduced in accordance with paragraphs (d)(1)(i) and (d)(1)(ii) of § 1.775. Half days will be ignored for purposes of subtraction.

(2) Adding the number of days determined in proposed paragraph (d)(1) to the original term of the patent as shortened by any terminal disclaimer;

(3) Adding 14 years to the date of approval of the application under section 351 of the Public Health Service Act, or subsection (b) of section 505 or section 507 of the Federal Food, Drug, and Cosmetic Act;

(4) Comparing the dates for the ends of the periods obtained from (d)(2) and (d)(3) with each other and selecting the earlier date;

(5) If the original patent issued after September 24, 1984:

 (i) By adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and

(ii) By comparing the dates obtained in paragraphs (d)(4) and (d)(5)(i) with each other and selecting the earlier date.

(6) If the original patent was issued before September 24, 1984:

(i) If no request was submitted for an exemption under subsection (i) of

section 505 or subsection (d) of section 507 of the Federal Food, Drug, and Cosmetic Act, by (A) adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer and (B) by comparing the dates obtained in paragraphs (d)(4) and (d)(6)(i)(A) with each other and selecting the earlier date:

(ii) If a request was submitted for an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, and Cosmetic Act, and the commercial marketing or use of the product was not approved before September 24, 1984, by (A) adding 2 years to the original expiration date of the patent or any earlier date set by terminal disclaimer, and (B) by comparing the dates obtained in paragraph (d)(4) and (d)(6)(ii)(A) with each other and selecting the earlier date.

Section 1.776, if added as proposed, would provide the procedure for calculating the patent term extension for a food additive or color additive. The paragraphs correspond to those

proposed for § 1.775.

Section 1.777, if added as proposed, would provide the procedure for calculating the patent term extension for a medical device. The paragraphs correspond to those proposed for § 1.775 with the major difference being in the calculation of the regulatory review period.

Section 1.780, if added as proposed. would specify that once a determination is made pursuant to proposed § 1.750 that a patent is eligible for extension, a certificate of extension, under seal, will be issued to the applicant for the extension of the term of the patent. Section 1.780 would also provide that the certificate would be recorded in the official file of the patent and will be considered as part of the original patent. Section 1.780 would also provide for notification of the issuance of the certificate of extension to be published in the Official Gazette of the Patent and Trademark Office.

No certificate or extension would be issued if the term of a patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations the final determination made pursuant to § 1.750 would indicate that no certificate will issue.

Section 1.785, if added as proposed, would specify the procedures to be followed where multiple applications are filed for extension of the same patent or of different patents for the same regulatory review period for a product. Pub. L. 98–417 and proposed § 1.785 provide that only one patent may

be extended for a regulatory review period for any product. Under proposed § 1.785, if more than one application for extension of the same patent is filed, the certificate of extension of the term of the patent, if appropriate, would be issued based upon the first filed application for extension of patent term. If applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension would be issued on the patent having the earliest date of issuance, if that patent is determined to be eligible for extension pursuant to proposed § 1.750 and if the application for its extension is filed prior to the issuance of a certificate of extension of the later issued patent.

Other alternatives to proposed § 1.785 were considered, but were not proposed in view of a number of complications which appeared to be present therein. For example, another alternative was to give preference to a patent owner who was also the marketing applicant before the FDA. However, neither patent owner may have been the marketing applicant, or each patent owner may have contributed resources which ultimately led to the approval for commercial marketing. In view of the complications which are apparent in the PTO attempting to make value judgments as to the relative contributions of different patent owners it was decided to propose an administratively straight forward approach and seek public comments as to other possible workable alternatives.

Environmental, energy, and other considerations: The rule change will not have a significant impact on the quality of the human environment or conservation of energy resources. The rule change is in conformity with the requirements of the Regulatory Flexibility Act (Pub. L. 96–354), Executive Order 12291, and the Paperwork Reduction Act of 1960, 44

U.S.C. 3501 et seq.

The General Counsel of the Department of Commerce certified to the Small Business Administration that the rule change will not have a significant adverse economic impact on a substantial number of small entities because patented drugs are generally not commercialized by small entities (Regulatory Flexibility Act, Pub. L. 96–364)

The Patent and Trademark Office has determined that this rule change is not a major rule under Executive Order 12291. The annual effect on the economy will be less than \$100 million.

There will be no major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic

regions. There will be no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The information collection requirement contained in this proposed rule has been submitted to OMB for review under section 3504(h) of the Paperwork Reduction Act. Comments relating to this requirement should be directed to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for Commerce, Patent and Trademark Office.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Authority delegations (government agencies), Conflict of interest, Courts, Inventions and patents, Lawyers.

Notice is hereby given that pursuant to the authority granted to the Commissioner of Patents and Trademarks by 35 U.S.C. 6 and Pub. L. 98-417, the Patent and Trademark Office is proposing to amend Title 37 of the Code of Federal Regulations as set forth below.

PART 1-[AMENDED]

 The authority citation for 37 CFR Part 1 continues to read as follows:

Authority: 35 USC 6, unless otherwise noted.

Section 1.1 is proposed to be amended by adding a new paragraph (f) to read as follows:

§ 1.1 All communications to be addressed to the Commissioner of Patents and Trademarks.

(f) All applications for extension of patent term and any communications relating thereto intended for the Patent and Trademark Office should be additionally marked "Box Patent Ext." When appropriate, the communication should also be marked to the attention of a particular individual, as where a decision has been rendered.

 Section 1.20 is proposed to be amended by adding a new paragraph (n) to read as follows:

§ 1.20 Post-issuance fees.

4. A new "Subpart F—Extension of Patent Term" is proposed to be added to read as follows:

Subpart F--Extension of Patent Term

Sec

- 1.710 Patents subject to extension of the patent term.
- 1.720 Conditions for extension of patent term.
- 1.730 Applicant for extension of patent term.

 1.740 Application for extension of patent
- term.
 1.750 Determination of eligibility for
- extension of patent term.
- 1.760 Interim extension of patent term.
 1.765 Duty of disclosure in patent term extension proceedings.
- 1.770 Express withdrawal of application for extension of patent term.
- Calculation of the patent term
 extension for a human drug product.

 Calculation of patent term for a food.
- additive or color additive.

 1.777 Calculation of patent term for a
- medical device.
- 1.780 Certificate of extension of patent term.
 1.785 Multiple applications for extension of term of the same patent or of different patents for the same regulatory review period for a product.

Authority: 35 USC 6 and 156.

Subpart F-Extension of Patent Term

§ 1.710 Patents subject to extension of the patent term.

(a) A patent is eligible for extension of the patent term if the patent claims a product as defined in paragraph (b) of this section, or a method of using such a product, or a method of manufacturing such a product, and meets all other conditions and requirements of this part.

(b) The term "product" referred to in paragraph (a) of this section means (1) a human drug product which means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or (2) any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

§ 1.720 Conditions for extension of patent term.

The term of patent may be extended if:

(a) The patent claims a product or a method of using or manufacturing a product as defined in § 1.710 of this part;

(b) The term of the patent has never been previously extended except for any interim extension issued pursuant to § 1.760 of this part;

(c) An application for extension is submitted pursuant to § 1.740 of this part: (d) The product has been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial

marketing or use;

(e) The product is an approved product, that is it has received permission for commercial marketing or use and (i) the application is submitted within the sixty day period beginning on the date the product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred, or (ii) in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension is submitted within the sixty day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent;

(f) The term of the patent has not expired before the submission of an application pursuant to § 1.740 of this

part; and

(g) No other patent has been extended for the same regulatory review period for the product.

§ 1.730 Applicant for extension of patent term.

Any application for extension of a patent term must be submitted by the owner of record of the patent or its agent and must comply with the requirements of § 1.740 of this part.

§ 1.740 Application for extension of patent term.

(a) An application for extension of patent term must be made in writing to the Commissioner of Patents and Trademarks. The filing date of an application for extension of patent term is the date on which the complete application for extension as set forth in paragraph (b) of this section, and a duplicate of the papers thereof, certified as such, are received in the Patent and Trademark Office or filed pursuant to the "Certificate of Mailing" provisions of 37 CFR 1.8 or "Express Mail" provisions of § 1.10 of this part.

(b) A complete application for the extension of patent term comprises:

(1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics;

(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred;

(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred:

(4) In the case of human drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food Drug and Cosmetic Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients) and the provision of law under which it was approved.

(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to § 1.720(e) and an identification of the date of the last day on which the application could be

submitted;

(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patient number, and the date of issue;

(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims)

and drawings;

(8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the

patent;

(9) A statement beginning on a new page that the patent claims the approved product or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which each applicable patent claim reads on the approved product or a method of using or manufacturing the approved product;

(10) A statement beginning on a new page of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review period as follows:

(i) For a patent that claims a human drug product, the effective date of the investigational new drug (IND) application and the IND number; the date on which a new drug application (NDA) was initially submitted and the NDA number; and the date on which the

NDA was approved;

(ii) For a patent that claims a food or color additive, the date a major health or environmental effects test on the additive was initiated and any available substantiation of that date; the date on which a petition for product approval under the Federal Food, Drug and Cosmetic Act was initially submitted

and the petition number; and the date on which the FDA published a Federal Register notice listing the additive for use:

(iii) For a patent that claims a medical device, the effective date of the investigational device exemption (IDE) and the IDE number; if applicable, or the date on which the applicant began the first clinical investigation involving the device if no IDE was submitted and any available substantiation of that date; the date on which an application for product approval under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted and the number of the application; and the date on which the application was approved.

(11) A brief description beginning on a new page of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities;

(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined;

(13) A statement that applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought (see § 1.765 of this part);

(14) The prescribed fee for receiving and acting upon the application for extension (see § 1.20(n) of this part);

- (15) The name, address, and telephone number of person to whom inquiries and correspondence relating to the application for patent term extension are to be directed; and
- (16) An oath or declaration as set forth in paragraph (c) of this section.
- (c) Any application for extension of the term of a patent submitted pursuant to paragraph (a) and (b) of this section must include an oath of declaration signed by the owner of record of the patent or its agent which specifically identifies the papers and the patent for which an extension is sought and avers that the person signing the oath or declaration:
- (1) Is the owner, an official of a corporate owner authorized to obligate the corporation, or has specific written authorization to sign the cath or declaration on behalf of the owner;
- (2) Has reviewed and understands the contents of the application being submitted pursuant to this section;

(3) Believes the patent is subject to extension pursuant to § 1.710 of this part:

(4) Believes an extension of the length claimed is fully justified under 35 U.S.C. 156 and the applicable regulations; and

(5) Believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in § 1.720 of this part.

(d) If any application for extension of patent term submitted pursuant to this section is held to be incomplete, applicant may seek to have that holding reviewed by filing a petition with the required fee pursuant to § 1.182 or § 1.183, as appropriate, within such time as may be set, or if no time is set, within one month of the date on which the application was held incomplete.

§ 1.750 Determination of eligibility for extension of patent term.

A determination as to whether a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for extension filed pursuant to § 1.740 of this part. This determination may be delegated to appropriate Patent and Trademark Office officials and may be made at any time before the certificate of extension is issued. The Commissioner or other appropriate officials may require further information before a final determination is made on whether a patent is eligible for extension. A notice will be mailed to applicant containing the determination as to the eligibility of the patent for extension and the period of time of the extension, if any. This notice shall constitute the final determination as to the eligibility and any period of extension of the patent. A single request for reconsideration of a final determination may be made if filed by the applicant within such time as may be set or, if no time is set, within one month from the date of the final determination.

§ 1.760 Interim extension of patent term.

An applicant who has filed a complete application for extension pursuant to § 1.740 of this part may request one or more interim extensions for periods of up to one year pending a final determination on the application pursuant to § 1.750 of this part. Any such request should be filed at least three months prior to the expiration date of the patent. The Commissioner may issue interim extensions, without a request by the applicant, for periods of up to one year until a final determination is made. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be eligible.

§ 1.765 Duty of disclosure in patent term extension proceedings.

(a) A duty of candor and good faith toward the Patent and Trademark Office and the Secretary of Health and Human Services rests on the patent owner or its agent, on each attorney or agent who represents the patent owner, and on every other individual who is substantively involved on behalf of the patent owner in a patent term extension proceeding. All such individuals who are aware, or become aware, of information material to the determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding must bring such information to the attention of the Office or the Secretary, as appropriate, in accordance with paragraph (b) of this section, as soon as it is practical to do so after the individual becomes aware of the information. Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding.

(b) Disclosures pursuant to this section must be accompanied by a copy of each written document which is being disclosed. The disclosure must be made to the Office or the Secretary, as appropriate, unless the disclosure is material to determinations to be made by both the Office and the Secretary, in which case duplicate copies, certified as such, must be filed in the Office and with the Secretary. Disclosures pursuant to this section may be made to the Office or the Secretary, as appropriate, through an attorney or agent having responsibility on behalf of the patent owner or its agent for the patent term extension proceeding or through a patent owner acting on his or her own behalf. Disclosure to such an attorney. agent or patent owner shall satisfy the duty of any other individual. Such an attorney, agent or patent owner has no duty to transmit information which is not material to the determination of entitlement to the extension sought.

(c) No patent will be determined eligible for extension and no extension will be issued if it is determined that fraud on the Office or the Secretary was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence in connection with the patent term extension proceeding. If it is established by clear and convincing evidence (1) that any fraud was practiced or attempted on the Office of the Secretary in connection

with the patent term extension proceeding or (2) that there was any violation of the duty of disclosure through bad faith or gross negligence in connection with the patent term extension proceeding, a final determination will be made pursuant to § 1.750 that the patent is not eligible for extension.

(d) The duty of disclosure pursuant to this section rests on the individuals identified in paragraph (a) of this section and no submission on behalf of third parties, in the form of protests or otherwise, will be considered by the Office. Any such submission by third parties to the Office will be returned to the party making the submission, or otherwise disposed of, without consideration by the Office.

§ 1.770 Express withdrawal of application for extension of term.

An application for extension of patent term may be expressly withdrawn before a determination is made pursuant to § 1.750 by filing in the Office, in duplicate, a written declaration of withdrawal signed by the owner of record of the patent or its agent. An application may not be expressly withdrawn after the date of the final determination on the application. An express withdrawal pursuant to this section is effective when acknowledged in writing by the Office. The filing of an express withdrawal pursuant to this section and its acceptance by the Office does not entitle applicant to a refund of the filing fee (§ 1.20(n)) or any portion thereof.

§ 1.775 Calculation of patent term extension for a human drug product.

- (a) If a determination is made pursuant to § 1.750 of this part that a patent for a human drug product is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer (§ 1.321).
- (b) The term of the patent for a human drug product will be extended by the length of the regulatory review period for the product as determined by the Secretary of Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(1)-(6) of this section.
- (c) The length of the regulatory review period for a human drug product will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(1)(B), it is the sum of

(1) The number of days in the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, and Cosmetic Act became effective for the approved human drug product and ending on the date an application was initially submitted for such drug product under those sections or under section 351 of the Public Health Service Act; and

(2) The number of days in the period beginning on the date the application was initially submitted for the approved human drug product under section 351 of the Public Health Service Act, subsection (b) of section 505 or section 507 of the Federal Food, Drug, and Cosmetic Act and ending on the date such application was approved under such section.

(d) The term of the patent as extended for a human drug product will be determined by

(1) Substracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(c)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence:

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of approval of the application under section 351 of the Public Health Service Act, or subsection (b) of section 505 or section 507 of the Federal Food, Drug, and Cosmetic Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting

the earlier date;

(5) If the original patent was issued

after September 24, 1984,

(i) By adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer;

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and

(d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before September 24, 1984,

If not request was submitted for an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, and Cosmetic Act, by (A) adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer and (B) by comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date;

(ii) If a request was submitted for an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, or Cosmetic Act and the commercial marketing or use of the product was not approved before September 24, 1984, by (A) adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and (B) by comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A of this section with each other and selecting the earlier date.

§ 1.776 Calculation of patent term extension for a food additive or color

(a) If a determination is made pursuant to § 1.750 of this part that a patent for a food additive or color additive is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or earlier date set by terminal disclaimer (§ 1.321).

(b) The term of the patent for a food additive or color additive will be extended by the length of the regulatory review period for the product as determined by the Secretary of Health and Human Service, reduced as appropriate pursuant to paragraph (d)(1)-(6) of this section.

(c) The length of the regulatory review period for a food additive or color additive will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. 156(g)(2)(B), it is the sum of

(1) The number of days in the period beginning on the date of major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the approved product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product; and

(2) The number of days in the period beginning on the date a petition was initially submitted with respect to the

approved product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(d) The term of the patent as extended for a food additive or color additive will

be determined by

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and 9c)(2) of this section which were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence;

(iii) The number of days equal to onehalf the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragrphs (d)(1)(i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by an terminal disclaimer;

(3) By adding 14 years to the date a regulation for use of the product became effective or, if objections were filed to such regulation, to the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, to the date such proceedings were finally resolved and commercial marketing was permitted;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting

the earlier date;

(5) If the original patent was issued after September 24, 1984,

(i) By adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and

(d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued

before September 24, 1984,

(i) If no major health or environmental effects test was initiated and no petition for a regulation or application for registration was submitted, by (A) adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer and (B) by comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date;

(ii) If a major health or environmental effects test was initiated or a petition for a regulation or application for registration was submitted, and the commercial marketing or use of the product was not approved before September 24, 1984, by (A) adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and (B) by comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier

date.

§ 1.777 Calculation of patent term extension for a medical device.

(a) If a determination is made pursuant to § 1.750 of this part that a patent for a medical device is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or earlier date as set by terminal disclaimer (§ 1.321).

(b) The term of the patent for a medical device will be extended by the length of the regulatory review period for the product as determined by the Secretary of Health and Human Services, reduced as appropriate pursuant to paragraphs (d)(1)-(6) of this

section.

(c) The length of the regulatory review period for a medical device will be determined by the Secretary of Health and Human Services. Under 35 U.S.C.

156(g)(3)(B), it is the sum of

(1) The number of days in the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act; and

(2) The number of days in the period beginning on the date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act, and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) of the Act and ending on the date the protocol was declared completed under section 515(f)(6) of the Act.

(d) The term of the patent as extended for a medical device will be determined

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period pursuant to paragraph (c) of this section:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1) (i) and (ii) of this section; half days will be ignored for purposes of subtraction:

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of approval of the application under section 515 of the Federal Food, Drug, and Cosmetic Act or the date a product development protocol was declared completed under section 515(f)(6) of the Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after September 24, 1984,

 (i) By adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before September 24, 1984,

(i) If no clinical investigation on humans involving the device was begun or no product development protocol was submitted under section 515(f)(5) of the Federal Food, Drug, and Cosmetic Act, by (A) adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer and (B)

by comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date:

(ii) If a clinical investigation on humans involving the device was begun or a product development protocol was submitted under section 515(f)(5) of the Federal Food, Drug, and Cosmetic Act and the commercial marketing or use of the product was not approved before September 24, 1984, by (A) adding 2 years to the original expiration date of the patent or earlier date set by terminal disclaimer, and (B) by comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

§ 1.780 Certificate of extension of patent term.

If a determination is made pursuant to § 1.750 of this part that a patent is eligible for extension and that the term of the patent is to be extended, a certificate of extension, under seal, will be issued to the applicant for the extension of the patent term. Such certificates will be recorded in the official file of the patent and will be considered as part of the original patent. Notification of the issuance of the certificate of extension will be published in the Official Gazette of the Patent and Trademark Office. No certificate of extension will be issued if the term of the patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations the final determination made pursuant to § 1.750 will indicate that no certificate will issue.

§ 1.785 Multiple applications for extension of term of the same patent or of different patents for the same regulatory review period for a product.

Only one patent may be extended for a regulatory review period for any product (§ 1.720(g)). If more than one application for extension of the same patent is filed, the certificate of extension of patent term, if appropriate, will be issued based upon the first filed application for extension. If applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product. the certificate of extension of patent term will be issued to the patent having the earliest date of issuance, if the patent is determined to be eligible for extension of patent term pursuant to § 1.750 and if the application for its extension is filed prior to the issuance of a certificate of extension of patent term of the later issued patent.

Dated: May 23, 1986.

Donald J. Quigg,

Assistant Secretary and Commissioner of Patents and Trademarks.

[FR Doc. 86-17054 Filed 7-29-86; 8:45 am] BILLING CODE 3510-16-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW-FRL-3057-1]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusions

AGENCY: Environmental Protection

ACTION: Proposed rule and request for comment.

SUMMARY: The Environmental Protection Agency (EPA) today is proposing to exclude the solid wastes generated at three facilities from the lists of hazardous wastes contained in 40 CFR 261.31 and 261.32. This action responds to delisting petitions submitted under 40 CFR 260.20, which allows any person to petition the Administrator to modify or revoke any provision of Parts 260 through 265, 124, 270, and 271 of Title 40 of the Code of Federal Regulations, and 40 CFR 260.22, which specifically provides generators the opportunity to petition the Administrator to exclude a waste on a "generator-specific basis" from the hazardous waste lists. The effect of this action, if promulgated, would be to exclude certain wastes generated at particular fcilities from listing as hazardous wastes under 40 CFR Part 261.

The Agency has previously evaluated each of these petitions which are discussed in today's notice. Based on our review at that time, these petitioners were granted a temporary exclusion. Due to changes to the delisting criteria required by the Hazardous and Solid Waste Amendments of 1984, however, these petitions have been evaluated both for the factors for which the wastes were originally listed, as well as other factors (including additional toxicants) which reasonably could cause the wastes to be hazardous.

DATES: EPA will accept public comments on these proposed exclusions until August 29, 1986. Comments postmarked after the close of the comment period will be stamped "late."

Any person may request a hearing on these proposed exclusions by filing a request with Bruce Weddle, whose address appears below, by August 14, 1986. The request must contain the information prescribed in 40 CFR 260.20(d).

ADDRESSES: Send three copies of your comments to EPA. Two copies should be sent to the Docket Clerk, Office of Solid Waste (WH–562), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. A third copy should be sent to Jim Kent, Delisting Section, Waste Identification Branch, CAD/OSW (WH–562B), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Idntify your comments at the top with this regulatory docket number: F–86–CPP-FFFFF.

Requests for a hearing should be addressed to Bruce Weddle, Director, Permits and State Programs Division, Office of Solid Waste (WH–563), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

The RCRA regulatory for these proposed exclusions is located at the U.S. Environmental Protection Agency, 401 M Street, SW. (Sub-basement), Washington, DC 20460, and is available for viewing from 9:30 a.m. to 3:30 p.m., Monday through Friday, excluding holidays. If you want to make an appointment call Mia Zmud at (202) 382–4675 or Kate Blow at (202) 382–4675. The public may copy a maximum of 50 pages of material from any one regulatory docket at no cost. Additional copies cost \$.20 per page.

FOR FURTHER INFORMATION CONTACT: RCRA Hotline, toll free at (800) 424– 9346, or at (202) 382–3000. For technical information, contract Lori DeRose, Office of Solid Waste (WH–563), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460 (202) 382–5096.

SUPPLEMENTARY INFORMATION:

Background

On January 16, 1981, as part of its final and interim final regulations implementing section 3001 of RCRA, EPA published amended lists of hazardous wastes from non-specific and specific sources. These lists have been amended several times, and are published in 40 CFR 261.31 and 261.32. These wastes are listed as hazardous because they typically and frequently exhibit any of the characteristics of hazardous wastes identified in Subpart C of Part 261 (i.e., ignitability, corrosivity, reactivity, and extraction procedure (EP) toxicity) or meet the criteria for listing contained in 40 CFR 261.11 (a)(2) or (a)(3).

Individual waste streams may vary, however, depending on raw materials, industrial processes, and other factors. Thus, while a waste that is described in these regulations generally is hazardous, a specific waste from an individual facility meeting the listing description may not be. For this reason, 40 CFR 260.20 and 260.22 provide an exclusion procedure, allowing persons the opportunity to demonstrate that a specific waste from a particular generating facility should not be regulated as a hazardous waste.

To be excluded, petitioners must show that a waste generated at their facility does not meet any of the criteria under which the waste was listed. (See 40 CFR 260.22(a) and the background documents for the listed wastes.) In addition, the Hazardous and Solid Waste Amendments of 1984 (HSWA) require the Agency to consider factors (including additional constituents) other than those for which the waste was listed, if there is a reasonable basis to believe that such additional factors could cause the waste to be hazardous. Accordingly, a petitioner also must demonstrate that the waste does not exhibit any of the hazardous waste characteristics, as well as present sufficient information for the Agency to determine whether the waste contains any other toxicants at hazardous levels. (See 40 CFR 260.22(a); section 222 of the Hazardous and Solid Waste Amendments of 1984, 42 U.S.C. 6921(f); and the background documents for the listed wastes.) Although wastes which are "delisted" (i.e., excluded) have been evaluated to determine whether or not they exhibit any of the characteristics of a hazardous waste, generators remain obligated to determine their waste remains non-hazardous based on the hazardous waste characteristics.

In addition to wastes listed as hazardous in 40 CFR 261.31 and 261.32. residues from the treatment, storage, or disposal of listed hazardous wastes also are eligible for exclusion and remain hazardous wastes until excluded. (See 40 CFR 261.3(c) and (d)(2).) Again, the substantive standard for "delisting" is: (1) That the waste not meet any of the criteria for which it was listed originally; and (2) that the waste is not hazardous after considering factors (including additional constituents) other than those for which the waste was listed, if there is a reasonable basis to believe that such additional factors are present and could cause the waste to be hazardous. Where the waste is derived from one or more listed hazardous wastes, the demonstration may be made with respect to each constituent or the waste mixture as a whole. (See 40 CFR 260.22(b).) Generators of these excluded treatment, storage, or disposal residues

remain obligated to determine whether these residues exhibit any of the hazardous waste characteristics on a periodic basis.

Approach Used to Evaluate Delisting Petitions

The Agency first will evaluate the petition to determine whether the waste (for which the petition was submitted) is non-hazardous based on the criteria for which the waste was originally listed. If the Agency believes that the waste is still hazardous (based on the factors for which the waste was originally listed), it will propose to deny the petition. If, however, the Agency agrees with the petitioner that the waste is nonhazardous with respect to the factors for which the waste was originally listed, it then will evaluate the waste with respect to other factors, if there is a reasonable basis to believe that such additional factors are present and could cause the waste to be hazardous.

The Agency is using a hierarchical approach in evaluating petitions for the other factors or contaminants (i.e., those listed in Appendix VIII of Part 261). This approach may, in some cases, eliminate the need for additional testing. The petitioner can choose to submit a raw materials list and process descriptions. The Agency will evaluate this information to determine whether any Appendix VIII hazardous constituents are used or formed in the manufacturing and treatment process and are likely to be present in the waste at significant levels. If so, the Agency then will request that the petitioner perform additional analytical testing. If the petitioner disagrees, he may present arguments on why the toxicants would not be present in the waste, or, if present, why they would pose no toxicological hazard. The reasoning may include descriptions of closed or segregated systems, or mass balance arguments relating volumes of raw materials used to the rate of waste generation. If the Agency finds that the arguments presented by the petitioner are not sufficient to eliminate the reasonable likelihood of the toxicant's presence in the waste at levels of regulatory concern, the petition would be tentatively denied on the basis of insufficient information. The petitioner then may choose to submit the additional analytical data on representative samples of the waste during the public comment period.

Rather than submitting a raw materials list, petitioners may test their waste for any additional toxic constituents that may be present and submit this data to the Agency. In this case, the petitioner should submit an explanation to why any constituents from Appendix VIII of Part 261, for which no testing was done, would not be present in the waste or, if present, why they would not pose a toxicological hazard.

In making a delisting determination, the Agency evaluates each petitioned waste against the listing criteria and factors cited in 40 CFR 261.11(a)(2) and (a)(3). Specifically, the Agency considers whether the waste is acutely toxic, as well as the toxicity of the constituents, the concentration of the constituents in the waste, their tendency to migrate and bioaccumulate, their persistence in the environment once released from the waste, plausible types of management of the waste, and the quantities of waste generated. In this regard, the Agency has developed an analytical approach to the evaluation of wastes that are landfilled and land treated. See 50 FR 7882 (February 26, 1985), 50 FR 48886 (November 27, 1985), and 50 FR 48943 (November 27, 1985). The overall approach, which includes a ground water transport model, is used to predict reasonable worst-case contaminant levels in ground water in nearby receptor wells (i.e., the model estimates the ability of an aquifer to dilute the toxicant from a specific volume of wastel.1 The land treatment model also has an air component and predicts the concentration of specific toxicants at some distance downwind of the facility. The compliance point concentration determined by the model then is compared directly to a level of regulatory concern. If the value at the compliance point predicted by the model is less than the level of regulatory concern, then the waste could be considered non-hazardous and a candidate for delisting. If the value at the compliance point is above this level, however, then the waste probably still will be copnsidered hazardous, and not excluded from Subtitle C control.

This approach evaluates the petitioned wastes by assuming reasonable worst-case land disposal scenarios. This approach has resulted in the development of a sliding regulatory scale which suggests that a large volume of waste exhibiting a particular extract level would be considered hazardous, while a smaller volume of the same waste could be considered non-

hazardous.2 The Agency believes this to be a reasonable outcome since a larger quantity of waste (and the toxicants in the waste) might not be diluted sufficiently to result in compliance point concentrations that are less than the levels of regulatory concern. The selected approach predicts that the larger the waste volume, the higher the level of toxicants at the compliance point. For wastes that are typically landfilled, the mathematical relationship (with respect to ground water) yields at least as six-fold dilution of the toxicant concentration initially entering the aquifer (i.e., any waste exhibiting extract levels equal to or less than six times a level of regulatory concern will generate a toxicant concentration at the compliance point equal to or less than that same level). Depending on the volume of waste, an additional five-fold dilution may be imparted, resulting in a total dilution of up to thrity-two times.

The Agency is using this approach as one factor in determining the potential impact of the unregulated disposal of petitioned waste on human health and the environment. The Agency has used this approach in evaluating each of the wastes proposed for exclusion in today's publication. As a result of this evaluation, the Agency is proposing to grant the petitions discussed in this notice.

It should be noted that EPA has not verified the submitted test data before proposing to grant these exclusions. The sworn affidavits submitted with each petition bind the petitioners to present truthful and accurate results. In addition, the Agency has initiated a spot sampling and analysis program to verify the representitive nature of the data for some percentage of the submitted petitions before final exclusions will be granted.

Finally, before the Hazardous and Solid Waste Amendments of 1984 were enacted, the Agency granted temporary exclusions without first requesting public comment. The Amendments specifically require the Agency to provide notice and an opportunity for comment before granting an exclusion. All of the exclusions proposed today will not become effective unless and until made final. A notice of final exclusion will not be published until all public comments (including those at requested hearings, if any) are addressed.

¹ The Agency recently proposed a similar approach, including a ground water transport model, as part of the land disposal restrictions rule (see 54 FR 1662, January 14, 1966). The Agency, however, has not completed its evaluation of the comments on this proposal. If a regulation is promulgated, using the ground water transport model, the Agency will consider revising the delisting analysis.

² Other factors may result in the denial of a petition, such as actual ground water monitoring data or spot check verification data.

Petitions

The proposed exclusions published today involve the following peitioners:

· Capitol Products Corporation, Harrisburg, Pennsylvania;

· Continental Can Company, Olympia, Washington;

 Whirlpool Corporation, Findlay, Ohio.

I. Capitol Products Corporation

A. Petition for Exclusion

The Capitol Products Corporation (Capitol), a subsidiary of Ethyl Corporation, located in Harrisburg, Pennsylvania, has petitioned the Agency to exclude their wastewater treatment sludge. The facility is involved in aluminum extrusion manufacturing and surface finishing for end uses primarily in the building materials trade. Capitol also uses some of its extrusions for use in patio door and window assemblies. The sludge is presently listed as EPA Hazardous Waste No. F019-Wastewater treatment sludges from the chemical conversion coating of aluminum. The listed constituents of concern for this waste are hexavalent chromium and cyanide (complexed). Capitol has petitioned to exclude its wastewater treatment sludge because it does not meet the criteria for which the

waste originally was listed. Based upon the Agency's review of their petition, Capitol was granted a temporary exclusion on March 18, 1981 (see 46 FR 17199). The basis for granting the exclusion was negligible concentrations of cyanide, and the low migration potential of chromium in the waste. Since that time, the Hazardous and Solid Waste Amendments of 1984 were enacted. In part, the Amendments require the Agency to consider factors (including additional toxicants) other than those for which the waste was listed, if the Agency has a reasonable basis to believe that such additional factors could cause the waste to be hazardous. (See section 222 of the Amendments, 42 U.S.C. 6921(f).) In anticipation of either enactment of this legislation or regulatory changes by the Agency, EPA requested additional information from Capitol. This information was submitted on April 30, 1984, November 13, 1985, and November 20, 1985. As a result, the Agency has reevaluated Capitol's petition to: (1) Determine whether the temporary exclusion should be made final based on the original listing criteria; and (2) determine if the waste is non-hazardous with respect to factors and toxicants other than the original listing criteria. Today's notice is the Agency's reevaluation of the petition.

Capitol has submitted a detailed description of its manufacturing and treatment processes (including schematic diagrams); 3 total constituent analyses and EP toxicity test results of the sludge for total chromium; and analytical results for total cyanide. Capitol also submitted total constituent analyses and EP toxicity test results for arsenic, barium, cadmium, lead, mercury, selenium, silver, and nickel; total sulfide analyses; and total oil and grease analyses on representative waste samples. Capitol further submitted a list of raw materials used in the manufacturing process. As noted above, the Agency requested this information to determine if toxicants, other than those for which the waste was originally listed, are present in the waste at levels of regulatory concern.

Capitol uses a manufacturing process that involves the cleaning and conversion coating of aluminum extrusions to prepare the surfaces for finishing and painting. Capitol claims that cyanide is not used in their process. The wastewater originating from this manufacturing process is treated by a continuous reduction-neutralization process that is controlled by automatic oxidation-reduction potential instruments. The wastewater treatment process involves pH adjustment with sulfuric acid, reduction of hexavalent chromium to a trivalent state with sulfur dioxide, and pH adjustment and chromium precipitation with lime. The effluent is clarified and flocculants are added to enhance sludge settling. The clarified sludge is collected by an offsite contractor, and stabilized (using a proprietary process) before disposal. Capitol petitioned the Agency to exclude its clarified wastewater treatment sludge. Capitol claims that its wastewater treatment sludge is nonhazardous due to the immobile nature of chromium and negligible levels of cyanide in the sludge. Capitol also believes that the waste is nonhazardous for any other reason.

Composite samples were collected from the clarifier recycle feed pump pipe outfall. Each composite sample was composed of grab samples collected hourly from the outfall over an 8-hour workshift. Capitol's demonstration originally was based upon sampling conducted in 1980. For the purposes of further sampling and analysis, additional samples were collected in 1984 and 1985. Overall, a total of 10 composite samples were collected and

analyzed for various parameters. Capitol claims that all of the samples collected are representative of any variation of the constituent concentrations in the waste because the samples were collected over an entire workshift. Capitol further claims that the manufacturing processes used at the facility are uniform and the use of raw materials does not vary substantially over time.

Total constitutent and EP toxicity analyses of the sludge for the listed constituents revealed the maximum concentrations reported in Table 1.

TABLE 1.-MAXIMUM CONCENTRATIONS (PPM)

Listed constituents	Total constitu- ent analyses	EP leachate analyses
Cr (total) CN (total) ²	5,900 0.55	10.20

Hexavalent chromium is listed as the constituent of concern for this waste; however, the concentration of total chromium is low enough to make a determination of hexavalent chromium unnecessary.
 Free and leachable cyanide tests were not required since cyanide is not used in the process and the total content was low.

Total constituent and EP toxicity analyses of the sludge for the non-listed EP toxic metals revealed the maximum concentrations reported in Table 2.

TABLE 2.—MAXIMUM CONCENTRATIONS (PPM)

Non-listed constituents	Total constitu- ent analyses	EP leachate analyses
As	<8	< 0.5
Ba	26	< 0.1
Cd	1	< 0.1
Pb	40	< 0.20
Hg	2	< 0.05
Nt	6	< 0.1
Se	<6	< 0.5
Ag	2	< 0.1

The maximum total oil and grease value reported was 0.2 percent. Capitol also submitted a list of all raw materials used in their manufacturing and wastewater treatment processes. This list indicated that no Appendix VIII hazardous constituents, other than those tested for, are used in the process and that formation of any of these constituents is highly unlikely. Capitol also provided test data indicating that the sludge is not ignitable, corrosive, or reactive. Capitol claims to generate approximately 264 cubic yards of sludge per year.

B. Agency Analysis and Action

Capitol has demonstrated that its waste treatment system produces a nonhazardous sludge. The Agency believes that the 10 composite samples collected from the clarifier outfall were nonbiased and adequately represent any

⁵ Capitol has claimed their raw materials list and process descriptions as confidential business information (CBI). This information is not available for public inspection.

variations that may occur in the waste stream petitioned for exclusion. The key factor that could vary toxicant concentrations in the waste would be the use of different raw materials due to changes in the product line being manufactured. Variation in raw materials can be expected either when the facility performs as a job shop or when the product line changes seasonally. The Agency believes that Capitol's sampling period was long enough to cover any scheduled changes in the product line, since the petitioner has verified that there is no significant seasonal variation in the process and the chemicals used do not vary. Accordingly, the samples are representative of the waste generated by Capitol at its Harrisburg, Pennsylvania facility.

The Agency has evaluated the mobility of the listed constituents from Capitol's waste using the vertical and horizonal spread (VHS) model. The VHS model generated compliance point values using the model's minimum waste generation rate of 475 cubic yards per year and the maximum reported extract levels as input parameters. The compliance point concentrations for the listed constituents are shown in Table 3.

TABLE 3.—VHS MODEL: CALCULATED
COMPLIANCE POINT CONCENTRATIONS (PPM)

Eisted constituents	Sludge	Regula- tory standards
Cr (total)	0.006	0.05

¹ Free and leachable cyanide tests were not required because total cyanide content was low. Leachable cyanide was calculated assuming a theoretical leaching of 100 percent and at a twenty-tote dilution (100 grams of solids diluted with 2.0 liters of water) of the maximum total constituents concentration of cyanide.

The sludge exhibited a chromium level (at the compliance point) below the National Interim Primary Drinking Water Standard and cyanide levels below the U.S. Public Health Service's suggested drinking water standard.⁶ The total cyanide levels in the waste are also below the air threshold limit set by the American Conference of Governmental Hygienists.⁷ The

petitioner claims that cyanide is not used in its processes. The Agency believes that the petitioner substantiated this claim in that the levels of total cyanide found in the sludge were negligible and probably a result of background and non-specific process contamination. These constituents, therefore, are not of regulatory concern.

The Agency also concluded, through using the VHS model, that no other EP toxic metals or nickel are present in the sludge at levels of regulatory concern (i.e., none are above any regulatory standard at the compliance point in the VHS model). The compliance point values generated from these extract levels are displayed in Table 4. Where the maximum reported extract levels were below the detection limit, the value of the detection limit was used in the model.

Capitol also presented test data on the sulfide content of their waste. The maximum sulfide content reported was 0.14 ppm. The waste, therefore, is not reactive because release of hydrogen sulfide through reaction with acid into a volume of air the same volume as the sludge would only produce about 0.14 to 0.28 ppm by volume of hydrogen sulfide in the air. The air threshold limit set by the American Conference of Governmental Industrial Hygienists for hydrogen sulfide is 10 ppm.8 Capital also has shown that the sludge does not demonstrate the characteristics of ignitability and corrosivity. The Agency also reviewed Capitol's raw material list and material safety data sheets for each component in the raw materials list. The Agency has concluded from this review that no other Appendix VIII hazardous constituents are present in the waste.

TABLE 4.—VHS MODEL: CALCULATED COMPLIANCE POINT CONCENTRATIONS (PPM)

Non-listed constituents	Studge	Regula- tory standards
As	<0.02 <0.003 <0.003 <0.003 <0.002 <0.003	0.05 1.0 0.01 0.05 0.002 0.35 0.01

¹ The petitioner did not detect selentum, at a detection limit of 0.5 ppm, using the EP loxicity test. This level generates a compliance-point concentration slightly above the regulatory standard, although the selentum leschate concentration actually may be much less. Since selentum was not detected, and the compliance-point concentration reflects the detection limit used, the Agency considered, as an alternative, the total concentration of selentum in the waste. The Agency calculated the compliance-point concentration using the reported maximum total concentration level of selentum, assumed that all of the selentum would leach.

and then applied the twenty-fold dilution, inherent in the EP test (see Table 2). Since this calculated compliance-point concentration for seterium, shown above (using this worst-case assumption), did not exceed the regulatory threshold, the Agency balleves seterium is not of regulatory concern for this waste.

The Agency believes that Capitol's treatment process generates a nonhazardous waste that should be excluded from hazardous waste control. The agency, therefore, proposes to grant an exclusion to Ethyl Corporation's subsidiary, Capitol Products Corporation, located in Harrisburg, Pennsylvania, for its dewatered sludge, as described in its petition. (The Agency notes that the exclusions remain in effect unless the waste varies from that originally described in the petition (i.e., the waste is altered as a result of changes in the manufacturing or treatment process).9 In addition. generators still are obligated to determine whether these wastes exhibit any of the characteristics of hazardous waste.)

II. Continental Can Company

A. Petition for Exclusion

Continental Can Company (Continental), located in Olympia, Washington, is involved in the manufacturing of seamless aluminum beverage cans. Continental has petitioned the Agency to exclude its treated sludge, presently listed as EPA Hazardous Waste No. F019-Wastewater treatment sludges from the chemical conversion coating of aluminum. The listed constituents of concern for EPA Hazardous Waste No. F019 are hexavalent chromium and cyanide. Continental has petitioned the Agency to exclude its waste because it does not meet the criteria for which it is listed.

Based upon the Agency's review of their petition, Continental's Olympia. Washington facility was granted a temporary exclusion in November, 1982 (see 47 FR 52676). The Agency's basis for granting the temporary exclusion (at that time) was the low levels in the waste of the constituents of concern. namely chromium (hexavalent) and cyanide (complexed). Since that time, the Hazardous and Solid Waste Amendments of 1984 were enacted. In part, the Amendments require the Agency to consider factors (including additional constituents) other than those for which the waste was listed, if the Agency has a reasonable basis to

^{*} See 50 FR 7882, Appendix I, February 28, 1985, for a detailed explanation of the development of the VHS model for use in the delisting program. See also the final version of the VHS model. 50 FR 48896, Appendix, November 27, 1985.

⁵ Capitol generates approximately 264 cubic yards per year, however, the VHS model specifies, a minimum waste generation rate of 475 cubic yards. See 50 FR 48900 (November 27, 1985) for a discussion of the minimum waste generation rate.

⁶ Drinking Water Standards, U.S. Public Health Service, Publication 946, 1962 (0.2 ppm).

[†] See Documentation of Threshold Limit Values for Substances in Workroom Air, American

Conference of Governmental Industrial Hygienists, third edition, 1971, Cincinnati, Ohio.

⁸ See footnote 7.

^{*} The current exclusion apply only to the processes covered by the original demonstrations. A facility may file a new petition if it alters its process. The facility must treat its waste as hazardous, however, until a new exclusion is granted.

believe that such additional factors could cause the waste to be hazardous (See section 222 of the Amendments, 42 U.S.C 6921(f).) As a result, the Agency has re-evaluated Continental's petition to: (1) Determine whether the temporary exclusion should be made final based on the original listing criteria; and (2) evaluate the wastes for factors (other than those for which the waste was listed) to determine whether the waste is non-hazardous. This notice presents the results of the Agency's re-evaluation of this petition.

Continental has submitted a detailed confidential description of their conversion coating process, waste treatment process, and material safety data sheets, and non-confidential description of their can drawing process and waste treatment process, all of which include schematic diagrams; total constituent analyses for total chromium and cyanide; EP toxicity test results for total chromium; and distilled water leach test results for cyanide. Continental also submitted total constituent analyses and EP toxicity test results for the non-listed metals: analyses for total oil and grease content; and data regarding the ignitability, corrosivity, and reactivity of the waste. Continental further submitted a list of raw materials used in their manufacturing process. The Agency requested this information, as noted above, to determine if hazardous constituents, other than those for which the waste was originally listed, are present in the waste at levels of regulatory concern.

Continental manufactures seamless aluminum beverage cans in a draw and iron process. Aluminum sheet coil, lubricated with an oil/water emulsion, is cut into circular blanks, drawn, ironed, and trimmed to specifications. The open cans are then conveyed through a six stage washing process. In the first stage, the oil/water emulsion is removed. The residual oil/water emulsion and the aluminum fines are then removed in the second stage acid rinse (hydrofluoric and sulfuric acids). The cans are then rinsed with water to remove any residual acid solutions in stage three. In stage four, a conversion coating consisting of: zirconium salts, nitric acid, hydrofluoric acid, phosphoric acid, and fluoboric acid, is applied. Only beverage cans which will contain beer undergo conversion coating.10 During the

remaining ninety percent of Continental's production, no conversion chemicals are applied, and the cans proceed through stage four without receiving the conversion coating. All cans then proceed to stage five for a water rinse and then to stage six for a final deionized water rinse.

Process wastewater generated by the six stage can washer and the regeneration of the deionizer is treated on site in a physical/chemical wastewater treatment system. The wastewater enters a 16,500 gallon equalization tank. The wastewater and a cationic polymer (to destabilize any oil emulsions) are pumped to an agitated neutralization tank. Hydrated lime slurry is added to maintain the pH at 8.2. The neutralized wastewater then flows by gravity to a flocculation tank where an anionic polymer is added; and then, again by gravity, flows to an inclined lamella plate clarifier. The solids settle to a bottom hopper and the effluent overflows to a holding tank, prior to discharge to a sanitary sewer.

The collected solids are continuously pumped from the bottom hopper to a gravity sludge thickener, where additional anionic polymer is added. The thickened sludge is then pumped from the bottom of the thickener to a sludge holding tank. The supernatant from the gravity thickener flows to a holding tank prior to discharge to the sanitary sewer. Finally, the sludge is pumped to a rotary vacuum filter coated with diatomaceous earth (filter aid), where the sludge solid's content is increased to eighty percent. The supernatant is pumped to a holding tank, prior to discharge to the sanitary sewer. Filter cake from the vacuum filter is collected in a small hopper which is dumped into a 12 cubic yard truck trailer as needed.

Four daily composites each consisting of 14 to 16 hourly grab samples which were directly from the vacuum filter's discharge chute, were taken on February 1, 2, 3, and 4, 1986.11 Hourly grab samples were placed in separate one quart plastic bags. The bags were sealed, labeled, and placed in a larger bag for storage. The grab samples were then sent to the laboratory, where 200 grams of filter cake material was taken from each hourly grab sample, and mixed to produce one daily composite sample. Continental claims that the samples collected are representative of any variation of the listed and non-listed constituent concentrations in its waste stream, since the samples were collected when the conversion coating process was active and had accounted for approximately seven percent of the total wastewater flow. Additionally, during this time, the deionizers had been regenerated twice. Furthermore, Continental claims that the use of raw materials does not vary over time, and that the constituent concentrations in the six stage can washer are tightly controlled with very little variability. Consequently, they believe that the samples collected and analyzed fully characterize their waste.

Total constituent and EP leachate analyses of the chemical conversion coating waste, generated from the filter press for the listed constituents. revealed the maximum concentrations reported in Table 1.

TABLE 1.—MAXIMUM CONCENTRATIONS (FILTER PRESS)

Listed constituents	Total constitu- ent analyses (mg/kg)	Leschate analyses (mg/l)
CN	<1.0 53.0	*1.2 <0.5

Hexavalent chromium is listed as the constituent of concern for this waste; however, the concentration of total chromium is low enough to make the determination of hexavalent chromium unnecessary.
 From distilled water leach test Distilled water is used rather than the normal acidic EP extraction medium to avoid the destruction of cyanide during the extraction procedure.

Total constituent and EP toxicity analyses of the filter press waste for the non-listed EP metals revealed the maximum concentrations reported in Table 2.

TABLE 2.—MAXIMUM CONCENTRATIONS (FILTER PRESS)

Listed constituents	Total constitu- ent analyses (mg/kg)	EP leschate analyses (mg/l)
As	14.7 7.2 2.9 13.0 <0.05 25.0 <0.8 1.1	<0.5 10 <0.1 <0.5 <0.02 <0.5 <0.1 <0.5

The waste's total oil and grease content ranged between 0.51 percent and 1.05 percent. Continental also submitted a list of raw materials used in their manufacturing process. This list indicated that no Appendix VIII hazardous constituents (other than those tested for) are used in the process; however, the formation of formaldehyde, as a degradation product, is likely. Continental adds Triadine 10, a biocide, to the lubricant/coolant (at approximately 500 ppm) used in the can

¹⁰ Normal production of beer cans account for approximately 10 percent of Continental's

¹¹ Continental's demonstration was initially based on one total constituent analysis for total chrome and cyanide.

drawing process. The Triadine 10 breaks down to form formaldehyde as an intermediate. Under the low pH maintained in the can washer, however, Continental claims that the formaldehyde completely decomposes to methanol and salts of methane (i.e., the formaldehyde will completely decompose if there is sufficient hydrogen ions to form methane and salts of methane). Continental also provided test data indicating that the sludge is not ignitable, corrosive, or reactive. Continental claims to generate a maximum of 410 cubic yards/year of waste filter cake from this process.

B. Agency Analysis and Action

Continental has sufficiently demonstrated that the filter cake generated at their Olympia, Washington facility is non-hazardous. Based on the data presented in Continental's petition, the Agency believes that the petitioner has adequately characterized the waste filter cake, and that the samples analyzed reflect the day to day variation in production. The Agency believes Continental's claim that the manufacturing and treatment processes are uniform and consistent are well substantiated since this facility does not perform as a job shop or have seasonal product variations. Thus, we consider the sampling procedures used by Continental to be adequate, and as such, no significant day to day variation in constituent concentrations was detected. A comparison of the total constituent concentration of each constituent, as well as an evaluation of the QA/QC data (spike concentrations and percent recovery data) did not detect any significant variability in the waste (i.e., the standard deviation was very low.)¹² The Agency therefore concludes that the analytical information provided by Continental is representative of the waste filter cake.

The Agency has evaluated the mobility of the constituents from Continental's waste filter cake using the vertical and horizontal spread (VHS) model. 13 The Agency's evaluation of Continental's 410 cubic yards of filter cake using the maximum EP extract levels for the constituents of concern in the VHS model generated the compliance point concentrations in Table 3. (Where concentrations were below the detection limits, the detection limit was used in the VHS model calculations).

TABLE 3.—VHS MODEL: CALCULATED
COMPLIANCE POINT CONCENTRATIONS (PPM)

Listed constituents	Filter press	Regula- tory standards
Cr (total)	<0.016 <0.031	0.05 0.20

The filter press sludge exhibited chromium levels (at the compliance point below the National Interim Primary Drinking Water Standard, and cyanide levels below the U.S. Public Health Services suggested drinking water standard.14 In addition, the low total cyanide levels in the waste filter cake could not exhibit free cyanide at levels expected to create a health hazard through inhalation. In particular, the total cyanide, and free cyanide and photo-degradable cyanide are not present in sufficient concentrations in order to volatilize at concentrations exceeding the workroom air threshold limit of 10 ppm set by the American Conference of Governmental Industrial Hygienists (ACGIH).15

The Agency has also concluded that there are no other hazardous inorganic or organic constituents present in the waste filter cake at levels of regulatory concern. The Agency's conclusions are based on the examination of Continental's raw materials, knowledge of the process, and analytical test results provided in the petition. The Agency believes Continental's equilibrium reaction analysis in which there is a sufficient concentration of hydrogen ions to allow the complete decomposition of Triadine 10 to formaldehyde and then to methanol and the salts of methanol. We conclude that formaldehyde, therefore, is not present in environmentally significant concentrations. The non-listed EP toxic metals were evaluated using the VHS model (see Table 4). Using these values, the Agency predicts levels at the compliance point to be significantly below the applicable regulatory standards.

TABLE 4.—VHS MODEL: CALCULATED COMPLIANCE POINT CONCENTRATION (PPM)

Non-listed constituents	Filter	Regula- tory standards
As	< 0.016	0.05
Ba	< 0.31	1.0
Cd	< 0.003	0.01
Pb	< 0.016	0.05
Hg	< 0.0006	0.002
Ni	< 0.016	0.35
Se	< 0.003	0.01
Ag	< 0.016	0.05

¹⁴ See footnote 6.

The Agency also has reviewed each of the chemical components used in each raw material as supplied by raw material lists and material safety data sheets (MSDS). The Agency has concluded from this review that no other Appendix VIII hazardous constituents are present in the petitioned waste. Lastly, the waste filter cake is not reactive, ignitable, or corrosive.

The Agency concludes that the waste filter cake is non-hazardous (for all reasons), and as such, should continue to be excluded from hazardous waste control. The Agency, therefore, proposes to grant a final exclusion to Continental's Olympia, Washington facility, for its dewatered conversion coating filter cake, as described in their petition. The Agency notes that the exclusions remain in effect unless the waste varies from that originally described in the petition (i.e., the waste is altered as a result of changes in the manufacturing or treatment process).16 In addition, generators still are obligated to determine whether these wastes exhibit any of the characteristics of hazardous waste.)

III. Whirlpool Corporation—Findlay Division

A. Petition for Exclusion

The Whirlpool Corporation (Whirlpool), at its Findlay, Ohio facility, is involved in manufacturing household clothes dryers and dishwashers. Whirlpool has petitioned the Agency to exclude the wastewater treatment sludges produced at the Findlay facility, presently listed as EPA Hazardous Waste No. F006-Wastewater treatment sludges from electroplating operations, except from the following processes: (1) Sulfuric acid anodizing of aluminum: (2) tin plating on carbon steel; (3) zinc plating (segregated basis) on carbon steel; (4) aluminum or zinc-aluminum plating on carbon steel; (5) cleaning/ stripping associated with tin, zinc, and aluminum plating on carbon steel; and (6) chemical etching and milling of aluminum.17 The listed constituents of concern for this waste are cadmium, hexavalent chromium, nickel, and cyanide (complexed).

Based upon the Agency's review of the petition, Whirlpool was granted a temporary exclusion for its process

¹² See Standard T-test in Biometry: The Principles and Practices of Statistics in Biological Research; Sokal, R. and Rohlf, F.J. 1969.

¹⁸ See footnote 4.

¹⁵ See footnote 7.

¹⁶ See footnote 9.

¹⁷ Whirlpool petitioned the Agency to exclude the vacuum filter cake and sludge contained in four surface impoundments at the Findlay facility. This notice discusses the Agency's proposed exclusion for the vacuum filter cake. The Agency's action regarding the four surface impoundments will be published in a later notice.

waste (filter cake) on August 6, 1981 (see 46 FR 40162). The basis for granting this exclusion (at that time) was the low concentration and immobile form of the constituents of concern, namely cadmium, chronium, nickel, and cyanide, in the waste. Since that time, the Hazardous and Solid Waste Amendments of 1984 [HSWA] were enacted. In part, the Amendments require the Agency to consider factors (including additional constituents) other than those for which the waste was listed, if the Agency has a reasonable basis to believe that such factors could cause the waste to be hazardous. (See section 222 of the Amendments, 42 U.S.C. 6921(f).) As a result, the Agency has re-evaluated Whirlpool's petition to: (1) Determine whether the temporary exclusion should be made final based on the original listing criteria; and (2) evaluate the waste for factors other than those for which the waste was listed originally to determine whether the waste is non-hazardous. Today's notice is the Agency's re-evaluation of Whirlpool's petition.

In support of their petition, Whirlpool submitted a detailed description of its manufacturing and treatment processes, including schematic diagrams;18 total constituent analyses and Oily Waste EP test results for cadmium, total chromium, and nickel; and total constituent and distilled water leach test results for cyanide. Whirlpool also submitted total constituent analyses and results from the Oily Waste EP test for arsenic, barium, lead, mercury, selenium, and silver; and total oil and grease analyses on representative waste samples. In addition, Whirlpool submitted a list of raw materials used in the manufacturing process. As noted above, the Agency requested this information to determine if hazardous constituents, other than those for which the waste was listed originally, are present in the waste at levels of regulatory concern.

In Whirlpool's manufacturing process, the steel surfaces of appliance parts are cleaned with alkaline solutions to remove oils and are pickled to remove scale and rust. The parts then are prepared for painting and porcelain enameling by applying phosphating rinses. Batch dumps and rinsewaters from these processes and from a parts washer are routed to the wastewater treatment system, which combines lime

neutralization, flocculation (with the addition of a polymer), clarification), and vacuum filtration.

Process waste (vacuum filter cake) samples were collected by taking daily grab samples of equal volume from the hopper into which the vacuum filter deposits filter cake during its normal daily operation. This procedure was followed during January and February 1986, and yielded four weekly composite samples for analysis. Preliminary analyses of Whirlpool's filter cake in 1985 indicated that nickel would tend to leach from this waste at excessive levels and contaminate ground water. In order to address this problem, Whirlpool incorporated premanent steps into its wastewater treatment system: First, the rate of recycling high-alkalinity sludges back through the system for re-treatment was reduced, and the flow rate of lime slurry into the wastewater was increased (Step One); then, clarifier sludges were treated with additional lime (approximately 1 percent) before vacuum filtration (Step Two). All of the samples collected in January and February 1986 were treated by this treatment regime.

Total constituent and Oily Waste EP leachate analyses of the samples for the constituents of concern and the non-listed EP toxic metals revealed the maximum concentrations reported in Tables 1 and 2, respectively. Oily Waste EP test results were used in the Agency's evaluation of Whirlpool's waste because the oil and grease content of the waste routinely was found to be between 7 and 11 percent, a concentration that is attributed largely to drawing oils removed from the steel before processing. 19 20

¹⁹ The Agency requested that Whirlpool perform the Oily Waste EP test on its waste because of the high levels of oil and grease present in the waste. The Agency has decided to use the Oily Waste EP test to determine the migratory potential of metals from wastes containing greater than 1 percent oil and grease content. See 49 FR 42591. October 23, 1984. See also Method 1330 in "Proposed Sampling and Analytical Methodologies for Addition to Test Methods for Evaluating Solid Waste," as referenced in 49 FR 38790, October 1, 1984.

TABLE 1.—MAXIMUM CONCENTRATIONS

Constituents	Total constitu- ent analyses (mg/kg)	Oily waste EP leachate analyses (mg/l)
Cd Cr (total) Ni CN	<1.0 310 2670 36	0.05 0.15 2.3 10.18

¹ From distilled water leach test. Distilled water is used rather than the normal acidic EP extraction medium to avoid the destruction of cyanide during the extraction procedure.

TABLE 2.—MAXIMUM CONCENTRATIONS

Non-listed constituents	Total constitu- ent analyses (mg/kg)	City waste EP leachate analyses (mg/l)
As	4.7	< 0.04
Ba	1960	<1.0
Pb	440	0.15
Se	<5	1 < 0.04
Ag	2	0.1
Hg	2	0.004

Different detection limits due to analyses taken at different times.

The Agency has inspected the material safety data sheets for chemicals used in whirlpool's processes and has identified several additional constituents that may be present in Whirlpool's waste: petroleum hydrocarbons, antimony, and formaldehyde. No other Appendix VIII constituents are likely to enter or be formed in the waste.

Samples of the waste did not demonstrate any of the characteristics of hazardous waste, (i.e., ignitability, corrosivity, or reactivity). Whirlpool claims to generate a maximum of 275 tons of vacuum filter cake annually.

B. Agency Analysis and Action

Whirlpool has demonstrated to the Agency that the treatment sludges generated are non-hazardous. The Agency believes that the weekly composites of the vacuum filter cake are representative of the processes that have generated the wastes, and are indicative of the wastes as disposed. The manufacturing and treatment processes that produced the waste are very consistent; in addition, the use of raw materials does not vary significantly. The Agency, therefore, believes that the vacuum filter cake samples are representative of the waste generated by Whirlpool.

The wastes in the petition were evaluated with the Agency's vertical and horizontal spread (VHS) model.²¹

¹⁸ Whirlpool has claimed the schematic diagrams of its manufacturing and treatment processes as Confidential Business Information (CBI). These diagrams are not available for public inspection.

²⁰ The Oily Waste EP uses two organic solvents in the extraction, and is believed by the Agency to be as stringent, and very likely more stringent, than the conventional EP test. Whirlpool's Oily Waste EP data is, therefore, considered to be at least equivalent to regular EP test data. The Agency also notes that the Oily Waste EP values were not corrected to account for the oil volume, as was allowed in the Agency's response to comments made on the VHS model (see 50 FR 48908, November 27, 1985). Whirlpool's data, therefore, represents a worst-case situation because the EP concentrations are higher than they would be if such a volume correction was made.

²¹ See footnote. 4.

The Agency's evaluation of whirlpool's wastes, using the maximum values for estimated annual sludge production/ sludge volume and maximum reported leachate concentrations as input parameters, has resulted in the maximum compliance point concentrations for the listed constituents exhibited in Table 3. The evaluation of these wastes for the nonlisted EP metals produced the values shown in Table 4.

TABLE 3.-VHS MODEL: CALCULATED COMPLIANCE POINT CONCENTRATIONS

Listed constituents	Process sludge (ppm)	Regula- tory standards (ppm)
Cd	0.0015	0.01
Cr	0.0046	0.05
Ni	0.071	0.35
CN	0.0056	0.2

TABLE 4.-VHS MODEL: CALCULATED COMPLIANCE POINT CONCENTRATIONS

Non-listed constituents	Process sludge (ppm)	Regula- tory standards (ppm)
As	< 0.0012	0.05
Ba	< 0.031	1.0
Рь	0.0046	0.05
Se	< 0.0012	0.01
Ag	0.0031	0.05
Hg	0.0001	0.002

The process sludge demonstrated cadmium and chromium levels below their respective National Interim Primary Drinking Water Standards (NIPDWS), cyanide levels below the U.S. Public Health Service's suggested drinking water standard;22 and nickel levels below the Agency's Interim Health Advisory.23 These constituents. therefore, are not of regulatory concern.

For the non-listed constituents, the process sludge yielded levels of arsenic, barium, lead, selenium, silver and mercury that are below their respective National Interim Primary Drinking Water Standards. The Agency also reviewed Whirlpool's material safety data sheets and identified three Appendix VIII constituents that could be present in Whirlpool's waste: petroleum hydrocarbons, antimony, and formaldehyde. Evaluation of the mass balance of Whirlpool's manufacturing and treatment processes indicates that these constituents each are present only

in trace quantities in additives used by Whirlpool as such, are not expected to be present in the waste at levels of

kerosene) were not evaluated for toxicity since they are not toxic Appendix VIII substances. Antimony is present in three additives used by Whirlpool; analyses found that antimony was present in maximum concentrations of approximately 300 ppm in the waste, of which 0.8 mg/l was found to be leachable (in the EP Test). The VHS model, when used to predict potential antimony concentrations in ground water, produces a compliance point value of 0.025 mg/l. This value compares favorably with the Agency's standard of 0.14 mg/l for antimony.24 Based on Whirlpool's testing, formaldehyde is not detected in the waste at a detection limit of <1 ppm. After the concentration of formaldehyde in the waste leachate is calculated with the Agency's general linear model (GLM), this value is then used in the VHS model to predict a compliance point concentration of 0.03 ppm.25 26 27 The Agency believes that these Appendix VIII constituents are not of regulatory concern.

The Agency's evaluation of the wastes described in Whirlpool's petition indicates that the process sludges, which are treated with a lime conditioning step prior to vacuum filtration, are nonhazardous (for all reasons), and as such should be excluded from regulatory control. The Agency, therefore, proposes to grant a final exclusion to Whirlpool Corporation for the process sludges generated at its Findlay, Ohio facility. (The Agency notes that the exclusions remain in effect unless the waste varies from that originally described in the petition (i.e., the waste is altered as a result of changes in the manufacturing or treatment process).28 In addition, generators still are obligated to determine whether these wastes exhibit any of the characteristics of hazardous

IV. Effective Date

This rule, if promulgated, will become

regulatory concern. The petroleum hydrocarbons (largely

effective immediately. The Hazardous and Solid Waste Amendments of 1984 amended Section 3010 of RCRA to allow

rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. That is the case here since this rule maintains, or reduces, rather than increases, the existing requirements for persons generating hazardous wastes. In light of the unnecessary hardship and expense which would be imposed on the petitioners by an effective date six months after promulgation and the fact that such a deadline is not necessary to achieve the purpose of Section 3010, we believe that these rules should be effective immediately. These reasons also provide a basis for making this rule effective immediately under the Administrative Procedure Act, purusant to 5 U.S.C 553(d).

V. Regulatory Impact

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This proposal to grant exclusions is not major since its effect is to reduce the overall costs and economic impact of EPA's hazardous waste management regulations. This reduction is achieved by excluding wastes generated at specific facilities from EPA's list of hazardous wastes, thereby enabling the facility to treat its waste as non-hazardous.

VI. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601-612, whenever an Agency is required to publish a general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis which describes the impact of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). The Administrator may certify, however, that the rule will not have a significant economic impact on a substantial number of small entities.

This amendment will not have an adverse economic impact on small entities since its effect will be to reduce the overall costs of EPA's hazardous waste regulations. Accordingly, I hereby certify that this proposed regulation will not have a significant economic impact on a substantial number of small entities.

This regulation, therefore, does not require a regulatory flexibility analysis.

VIII. List of Subjects in 40 CFR Part 261

Hazardous waste, Recycling.

22 See footnote 8.

²⁴ Clean Water Act, Water Quality Criteria for Human Health see 40 FR 79325

²⁵ The Agency's GLM model is explained in detail in 50 FR 48955-56. November 27, 1985.

²⁶ See footnote 4.

²⁷ See 50 FR 48915, November 27, 1985, for analysis used by the Agency regarding the toxicity of formaldehyde.

²⁸ See footnote 9.

²³ The Agency previously used 632 ppb as the regulatory standard for nickel. Pending the completion of current EPA studies on the health effects of nickel, the Agency is using 350 ppb for the purpose of evaluating delisting petitions. The basis for this standard is explained at 50 FR 20239-48, May 15, 1985.

Dated: July 22, 1986. Marcia Williams,

Director, Office of Solid Waste.

For the reasons set out in the preamble, 40 CFR Part 261 is proposed to be amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for Part 261 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3001, and 3002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended [42 U.S.C. 6905, 6912(a), 6921, and 6922].

2. In Appendix IX, add the following wastestreams in alphabetical order:

Appendix IX—Wastes Excluded Under §§ 260.2. and 260.22.

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
Capitol Products Corp.	Harrisburg, PA	Dewatered wastewater treatment studge (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum after Linsert date of final rule publication]
Continental Can	Olympia, WA	Dewatered wastawater treatment sludge (EPA Hazardous Waste No. F019) generated from the chemical conversion coating of aluminum after [insert date of final rule publication].
Whirlpool Corp	Findlay, OH	Dewatered filter cake (EPA Hazardous Waste No. F006) generated from electroplating operations after [insert date of final rule publication].

[FR Doc. 86-17072 Filed 7-29-86; 8:45 am] BILLING CODE 6560-50-M

DEPARTMENT OF DEFENSE

48 CFR Part 213

Federal Acquisition Regulation Supplement on Small Purchase Procedures

AGENCY: Department of Defense (DoD), ACTION: Proposed rule and request for comments,

SUMMARY: The Defense Acquisition Regulatory Council is considering a change to the DoD FAR Supplement at 213.101(c) to exclude labor-surplus area set-asides from small purchase procedures.

DATE: Comments on the proposed revision should be submitted in writing to the Executive Secretary, DAR Council, at the address shown below, on or before September 29, 1986, to be considered in the formulation of the final rule. Please cite DAR Case 85–201 in all correspondence related to this issue.

ADDRESS: Interested parties should submit written comments to: Defense Acquisition Regulatory Council, ATTN: Mr. Charles W. Lloyd, Executive Secretary, ODASD(P)/DARS, c/o OASD(A&L), Room 3C841, The Pentagon, Washington, DC 20301-3062.

FOR FURTHER INFORMATION CONTACT: Mr. Charles W. Lloyd, Executive Secretary, DAR Council, telephone (202) 697–7268.

SUPPLEMENTARY INFORMATION:

A. Background

The Civilian Agency Acquisition Council proposed a change to FAR Part 13 (51 FR 23396, 26 June 1986), that, if implemented, would delete, for the Department of Defense, the exclusion of total small business and labor-surplus area set-asides from the requirements of FAR Part 13. Since DoD cannot make total labor-surplus area set-aside contracts regardless of dollar amount, this proposed change to the DoD FAR Supplement Section 213.101 would reinstate the exclusion of total small business and labor-surplus area setasides under Part 213 for DoD activities. This proposed change is considered to be internal to DoD and is not required to be published for public comment under Pub. L. 98-577. However, any comments submitted on or before the expiration date listed above will be considered in the formulation of a final rule.

B. Regulatory Flexibility Act Information

Since the proposed change is not required to be published for public comment under Pub. L. 98–577, the Regulatory Flexibility Act does not apply.

C. Paperwork Reduction Act Information

The proposed rule does not contain information collection requirements which require the approval of OMB under 44 U.S.C. 3501 et seq.

List of Subjects in 48 CFR Part 213

Government procurement.

Charles W. Lloyd,

Executive Secretary, Defense Acquisition Regulatory Council.

Therefore, it is proposed that 48 CFR Part 213 be amended as follows:

PART 213—SMALL PURCHASE AND OTHER SIMPLIFIED PURCHASE PROCEDURES

 The authority citation for 48 CFR Part 213 continues to read as follows:

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, and DoD FAR Supplement 201.301.

2. Section 213.101(c) is added to read as follows:

213.101 Definitions.

(c) For DoD activities the term "small purchase procedures" excludes laborsurplus area set-asides (see Part 220).

[FR Doc. 86–17063 Filed 7–29–86; 8:45 am]
BILLING CODE 3810-01-M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 172, 173, 174, 176, 177, 178, and 179

[Docket No. HM-166U; Notice No. 86-3]

Transportation of Hazardous Materials; Proposed Miscellaneous Amendments

AGENCY: Research and Special Programs Administration (RSPA), DOI.

ACTION: Extension of time to file comments.

SUMMARY: On June 3, 1986, RSPA published a notice of proposed rulemaking (Docket No. HM-166U, Notice No. 86-3; 51 FR 19866) concerning numerous changes to 49 CFR. Petitions have been received requesting additional time in which to evaluate and comment on the proposals in the notice. RSPA believes that an extension is consistent with the public interest and, by this notice, is extending the comment period from July 31, 1986, to September 4, 1986.

DATE: Comments must be received on or before September 4, 1986.

ADDRESS: Address comments to the Dockets Branch, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Darrell L. Raines, Chief, Exemptions and Regulations Termination Branch, Office of Hazardous Materials Transportation, Washington, DC 20590. Telephone (202) 366-4482

Issued in Washington, DC on July 18, 1988. under authority delegated in 49 CFR Part 106, Appendix A.

Alan I. Roberts,

Director, Office of Hazardous Materials Transportation.

[FR Doc. 86-17130 Filed 7-29-86; 8:45 am] BILLING CODE 4910-60-M

National Highway Traffic Safety Administration

49 CFR Part 531

[Docket No. FE-85-01; Notice 5]

Passenger Automobile Average Fuel **Economy Standards; Model Years** 1987-88

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation. **ACTION:** Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: NHTSA is nearing completion of its rulemaking proceeding in which it proposed to amend the passenger car fuel economy standards for model years (MY) 1987 and 1988). NHTSA has tentatively decided to reject the argument put forth by General Motors (GM) that the agency may (or indeed, must) consider a company's need for carryback credits in determining the maximum feasible average fuel economy level, and wishes to obtain public comment on this tentative conclusion. NHTSA also wishes commenters to address whether their position on this issue would differ if adoption of the GM argument would necessitate establishing the standard below 26.0 mpg for either or both model vears.

DATE: Comments on this notice must be received on or before August 14, 1986. Because of the need to complete this proceeding by the beginning of MY 1987, NHTSA will not consider any extension of this date, nor will it be able to consider late-filed comments.

ADDRESS: Comments should refer to the docket and notice numbers set forth above and be submitted to: Docket Section, Room 5109, 400 Seventh Street, SW., Washington, DC 20590. Docket hours are 8:00 a.m. to 4:00 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Ms. Erika Z. Jones, Chief Counsel,

National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590 (202-366-9511).

SUPPLEMENTARY INFORMATION: On January 22, 1986, NHTSA published in the Federal Register (51 FR 2912) a notice of proposed rulemaking (NPRM) to amend the MY 1987-88 passenger automobile average fuel economy standards, within a range of 26.0 mpg to 27.5 mpg for each model year.

Section 502(a)(4) of the Motor Vehicle Information and Cost Savings Act (the "Cost Savings Act") provides that, for MY 1985 or thereafter, the Secretary of transportation may amend the 27.5 mpg average fuel economy standard specified for passenger automobiles, if he or she determines that some other standard represents the maximum feasible average fuel economy level for that model year. In determining maximum feasible average fuel economy, the Secretary is required under section 502(e) of the Act to consider four factors: technological feasibility, economic practicability, the effect of other Federal motor vehicle standards on fuel economy, and the need of the nation to conserve energy.

While a separate fuel economy standard is set for each model year, the Cost Savings Act does not require absolute achievement of the standard within each year. Instead, it allows a shortfall for one year to be offset if a manufacturer exceeds the standard for another year or years. Under the act, as amended by the Automobile Fuel Efficiency Act of 1980, manufacturers earn credits for exceeding average fuel economy standards and may carry them back for three model years or forward

for three model years.

In concluding its analysis of the issues and data associated with its proposal to amend the passenger car fuel economy standards for MY 1987 and 1988. NHTSA wishes to obtain public comment on an issue that bears directly on the level of the standards to be set

for those two years.

GM has presented an argument that NHTSA may (or indeed, must) take into account the industry's need to earn "carryback credits" to offset prior year shortfalls when the agency determines the maximum feasible fuel economy level in a particular model year. GM first presented this argument in the MY 1986 passenger car standard rulemaking. See Docket FE-85-01-N01-051. GM later refined its arguments in subsequent filings. See Attachment 1 to Docket FE-85-01-N02-074; Docket FE-85-01-N04-2591 (Appendix I, pp. 66-81).

In its Preliminary Regulatory Impact Analysis for the MY 1986 standard (MY

1986 PRIA), NHTSA tentatively rejected the GM argument. See Docket FE-85-01-N02-006 (pp. I-21 to I-33). In establishing the standard for that year, however, the agency determined that it was not necessary at that time to reach a final conclusion on the issue of the need to earn carryback credits. See 50 FR 40548, October 4, 1985; MY 1986 Final Regulatory Impact Analysis, pp. I-32 to I-33 (Docket FE-85-01-N03-003).

Now, in concluding the proceeding for the MY 1987-1988 standards, the agency would like to have the benefit of public comments focused specifically on the issue of whether it may consider the need to earn carryback credits in establishing the maximum feasible fuel economy level in these two model years.

While the agency has reconsidered the argument that the carryforward/ carryback credit provisions make the determination of maximum feasible fuel economy level a multi-year concept, it has tentatively concluded once again that GM's argument appears to be inconsistent with both the language and

purposes of the Act.

The primary argument made by GM is that a standard is economically impracticable if it does not permit manufacturers to earn sufficient carryback credits to avoid noncompliance with past standards, at least to the extent such manufacturer has taken reasonable steps to attain the Act's technological goals. According to that company, "a standard that puts manufacturers at risk of large-scale noncompliance with the Act, and thus imposes the impossible predicament of choosing between heavy penalties and plant closures, cannot be considered 'feasible' or 'economically practicable' in any sense of those words, even though the finding of noncompliance, as an artifact of the credit system, technically relates to a previous model year." Docket FE-85-01-N01-051 (p. 12). In its comments on the MY 1987-88 NPRM, GM argued that "(i)t would not meet the test of 'economic practicability' to set standards for 1987 and 1988 that would require layoffs and plant closings to enable compliance with 1985 requirements." Docket FE-85-01-N04-2591 (p. 13).

The agency tentatively concludes that GM's argument is inconsistent with the plain meaning of the section 502(a)(4) and the overall statutory scheme.

Section 502(a)(4) of the Cost Savings Act states that, for model year 1985 and any subsequent model year, NHTSA may amend the 27.5 mpg standard to any higher or lower level that it determines is the "maximum feasible average fuel economy level for such

model year." (Emphasis added.) Each model year appears to be treated separately, and the relevant inquiry in determining the "maximum feasible average fuel economy level" appears to be the fuel economy level manufacturers are able to achieve in a particular model year, taking account of the four factors of section 502(e) NHTSA articulated this interpretation in the MY 1966 PRIA.

GM responded to this point by arguing that NHTSA's interpretation was "form over substance." GM suggested that another interpretation of the phrase "for such model year" is that the phrase simply refers back to the model year standard being amended and has no bearing on the grounds for the "maximum feasible" determination. The agency believes, however, that such an interpretation would imply that the words "for such model year" are redundant, contrary to accepted principles of statutory construction.

NHTSA also tentatively concludes that a construction of the Act that makes maximum feasible average fuel economy level a multi-year concept is contrary to the purposes of Congress in establishing, and later expanding, the credit provisions. The legislative history of the 1980 amendments (which expanded the credit availability from one to three years in each direction) indicates that the objectives of the new credit provision were to provide improved compliance flexibility, and to provide incentives for manufacturers to exceed the standards. H.R. Rep. No. 96-1026, 96th Cong., 2d Sess. at 19 (1980). There is no indication that Congress intended that NHTSA could consider the need for credits in any amendment it might promulgate; indeed, all indications are that the 1980 amendments were not intended to be used to justify relaxation of the standards. For example, the House Report noted that DOT had assured the Committee that the provision would not reduce fuel economy and emphasized that the Committee believe that the changes would "act as an incentive to manufacturers to exceed the standards now being set whenever they can in order to build up credits to act as safeguards against shortfalls that might occur in the future." H.R. Rep. No 96-

Representative Sharp, who introduced the amendments to the carryforward/ carryback provisions, emphasized the following:

The bills before us today are aimed at providing some flexibility in the administration of the standards program. None affect the fuel economy standards or the statutory mandate to comply with them. The standards remain untouched, as they

should. (Emphasis added.) H.R. Rep. No. 96– 1026 at 10, quoting a statement made by Representative Sharp at the Subcommittee on Energy and Power's hearings of March 28.

Representative Stockman, a supporter of the amendments, stated that the changes would permit "flexibility in terms of year-to-year compliance."
Cong. Rec., June 3, 1980, at 4421. Mr. Stockman also emphasized that "(a)s [the provisions] will result in greater flexibility to the manufacturers but not a relaxation of the regulations, [they] will result in the more economic production of fuel efficient automobiles. Cong. Rec., June 3, 1980, at 4422 (Emphasis added).

NHTSA observes that, in the short run, adoption of GM's argument would result in a standard lower than one calculated on a single-year basis, in apparent contradiction of the legislative history's guidance that the amendments would not result in any relaxation of the regulations. Indeed, adoption of this argument would likely result in a standard below 26.0 mpg.

Moreover, NHTSA believes that in the long run, manufacturer flexibility would be significantly reduced by a multi-year approach since such a construction of the Act would set a precedent permitting the setting of higher standards in future proceedings. Unless NHTSA concludes that credits should ordinarily be irrelevant in standard-setting, standards could be set at a higher level than indicated by a given model year's fuel economy capability, since projected future credits would simply be factored into the determination of maximum feasible average fuel economy level for the year in question.

GM argued that a single-year approach could require NHTSA to raise the standard for a future model year whenever manufacturers have projected CAFE surpluses for the year to offset a current shortfall, which would amount to writing the carryback credit provisions out of the Act entirely. The agency disagrees. Under the statute, any amendment making a fuel economy standard more stringent must be issued no later than 18 months before the start of the model year. The statute provides that a carryback plan may be submitted by a manufacturer in response to a notification from NHTSA of an apparent shortfall. This notification is based on data provided by the Environmental Protection Agency, ordinarily many months after the end of the model year in question. By the time a company submitted a three-year carryback plan in response to an agency notification concerning an apparent shortfall, the agency would be out of time to conduct a rulemaking to raise the standard even

for the third year addressed in the carryback plan. Moreover, if a company chose to exercise the option of submitting a three-year carryback plan for approval before the end of a model year, the decision of whether to raise the standards above 27.5 mpg for any of the future years addressed in the carryback plan would be within NHTSA's discretion. Thus, the agency would not be "required" to increase the standards in such a situation.

GM also argued that NHTSA's approach in setting the MY 1981–84 standards is supportive of its position. In that rulemaking, the agency considered setting higher standards than those ultimately selected, observing that the higher levels would have resulted in "no net civil penalty" liability for GM, Ford or Chrysler. See 42 FR 33547–8, June 30, 1977. NHTSA considered this issue in connection with the following guidance from the Conference Report:

Such determination [of maximum feasible average fuel economy level] should therefore take industrywide considerations into account. For example, a determination of maximum feasible average fuel economy should not be keyed to the single manufacturer which might have the most difficulty achieving a given level of fuel economy. Rather, the Secretary must weigh the benefits to the nation of a higher average fuel economy standard against the difficulties of individual automobile manufacturers. . . S. Rep. No. 94–516, 94th Cong., 1st Sess. 154–5 (1975).

NHTSA does not believe that the 1977 preamble statement is supportive of GM's position. The agency has never interpreted "maximum feasible average fuel economy level" to be a multi-year concept in the manner suggested by GM for the current rulemaking. The agency's 1977 discussion of "no net civil penalty was an observation about the potential effects on any individual manufacturer of an industrywide standard that may have exceeded the capability of one (or more) of them in a given year. In other words, it represented one method adopted by the agency to "take industrywide considerations into account" and "weigh the benefits to the nation of a higher average fuel economy standard against the difficulties of individual automobile manufacturers."

In subsequent fuel economy decisions for both light trucks and cars, NHTSA has made clear that it views the statute as requiring it to set a model year standard at a level that can be met that year by manufacturers whose vehicles constitute a substantial share of the market. In its determinations of maximum feasible average fuel economy level, the agency has consistently

analyzed the ability of manufacturers to meet a standard without regard to the ability to pay penalties for not meeting a standard, or the availability of, or need for, credits.

Because the resolution of this issue will affect the numerical level selected by NHTSA as the maximum feasible, the agency wishes to obtain public comments focused specifically on its tentative conclusion as outlined above and also discussed in the MY 1986 PRIA. The agency notes that it may reverse its position, if the comments persuade it to do so. NHTSA also wishes commenters to address whether their position on this issue would differ if adoption of the GM argument would necessitate establishing the standard below 26.0 mpg for either or both model years. Because of the need to complete this proceeding by the beginning of MY 1987, the agency can permit only a brief comment period. The agency cannot consider any extension of time, nor can it consider late-filed comments.

Analyses

NHTSA considered the impacts of the proposal to amend the MY 1987 and 1988 passenger automobile average fuel economy standards in the NPRM and determined that it was major within the meaning of Executive Order 12291 and significant within the meaning of the DOT Regulatory Policies and Procedures. A Preliminary Regulatory Impact Analysis (PRIA) was prepared and placed in the public rulemaking docket. As part of that rulemaking, this SNPRM remains major and significant.

The agency has also considered the economic impacts of the proposal for the purposes of the Regulatory Flexibility Act. I certify that the proposal would not have a significant economic impact on a substantial number of small entities. As indicated in the NPRM, no passenger car manufacturer subject to the proposed rule would be classified as a "small business" under the Regulatory Flexibility Act. In the case of small businesses, small organizations, and small governmental units which purchase passenger cars, adoption of the proposed rule would not affect the availability of fuel efficient passenger cars or have a significant effect on the overall cost of purchasing and operating passenger cars.

Pursuant to the National
Environmental Policy Act, the agency
also prepared an environmental
assessment concerning the proposal at
the time of the NPRM. A copy of that
document has been placed in the public
docket.

Public Comments

Interested persons are invited to submit comments on the proposal. It is requested but not required that 10 copies be submitted.

All comments must not exceed 15 pages in length. (49 CFR 553.21)
Necessary attachments may be appended to these submissions without regard to the 15-page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the agency's confidential business information regulation. (49 CFR Part

All comments received before the close of business on the comment closing date indicated above for the proposal will be considered, and will be available for examination in the docket at the above address both before and after that date. As indicated above. because of the need to complete this proceeding by the beginning of May 1987, the agency cannot consider latefiled comments. Comments on the proposal will be available for inspection in the docket. The NHTSA will continue to file relevant information as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

These persons desiring to be notified upon receipt of their comments in the rules docket should enclose a self-addressed, stamped postcard in the envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

List of Subjects in 49 CFR Part 531

Energy conservation, Fuel economy, Gasoline, Imports, Motor vehicles.

(15 U.S.C. 2002, delegation of authority at 49 CFR 1.50)

Issued on July 28, 1986.

Diane K. Steed,

Administrator.

[FR Doc. 86-17209 Filed 7-28-86; 12:36 pm]

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. MC-43 (Sub-No. 19)]

49 CFR Part 1057

Lease and Interchange of Vehicles (Documents in Lieu of Rated Freight Bills)

AGENCY: Interstate Commerce Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission proposes to revise 49 CFR 1057.12(g). The present regulation requires that leases between authorized carriers and owner-operators include a provision that the carrier provide a copy of the rated freight bill before or at the time of settlement to those owner-operators whose revenue is based on a percentage of the gross revenue for a shipment. The proposed rule would allow carriers the option of providing either: (1) A copy of the rated freight bill (or, in the case of contract carriers, another form of documentation); or (2) an alternative, computergenerated document that contains the same information that would appear on a rated freight bill.

DATE: Comments are due on September 15, 1986.

ADDRESS: Send an original and, if possible, 10 copies of comments referring to Ex Parte No. MC-43 (Sub-No. 19) to: Case Control Branch, Office of the Secretary, Interstate Commerce Commission, Washington, DC 20423

FOR FURTHER INFORMATION CONTACT:

Paul W. Schach (202) 275-7885

OI

Mark Shaffer (202) 275-7805

SUPPLEMENTARY INFORMATION:

Additional information is contained in the Commission's decision. To obtain a copy of the full decision, write to Office of the Secretary, Room 2215, Interstate Commerce Commission, Washington, DC 20423, or call (202) 275–7428.

Environmental and Energy Considerations

This action does not appear to affect significantly either the quality of the human environment or the conservation of energy resources.

Initial Regulatory Flexibility Analysis

The Commission certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. It should

reduce, albeit only minimally, administrative costs for many carriers.

Index

The index terms for 49 CFR Part 1057 are as follows: motor carriers, owner-operators, and equipment leasing.

Decided: July 22, 1986.

By the Commission, Chairman Gradison, Vice Chairman Simmons, Commissioners Sterrett, Andre, and Lamboley. Commissioner Andre concurred with a separate expression. Noreta R. McGee,

Secretary.

Appendix

Title 49 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1057-[AMENDED]

 The authority citation for 49 CFR Part 1057 would continue to read as follows:

Authority: 49 U.S.C. 11107 and 10321, 5 U.S.C. 553.

Paragraph (g) of § 1057.12 is proposed to be amended as follows:

§ 1057.12 Written lease requirements.

(g) Copies of Freight Bill or Other Form of Freight Documentation. When a lessor's revenue is based on a percentage of the gross revenue for a shipment, the lease must specify that the authorized carrier will give the lessor, before or at the time of settlement, a copy of the rated freight bill or a computer-generated document containing the same information, or, in the case of contract carriers, any other form of documentation actually used for a shipment containing the same information that would appear on a rated freight bill. When a computergenerated document is provided, the lease will lessor to view, during normal business hours, a copy of any actual document underlying the computergenerated document. Regardless of the method of compensation, the lease must permit lessor to examine copies of the carrier's tariff or other document from which rates and charges are computed. The authorized carrier may delete the names of shippers and consignees shown on the freight bill, or other form of documentation. * * *

[FR Doc. 86-17088 Filed 7-29-86; 8:45 am] BILLING CODE 7035-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 630

[Docket No. 50581-6137]

Atlantic Swordfish Fishery

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce. ACTION: Notice of preliminary annual adjustment to variable season closure.

SUMMARY: The Secretary of Commerce issues a notice of preliminary annual adjustment to the variable season closure (VSC) in accordance with the framework procedure specified in the Fishery Management Plan for Atlantic Swordfish. The VSC must be adjusted annually to reflect the most recent year's estimated catch of small swordfish. The intended effect is to reduce the catch of small fish to the 1980 level thereby increasing economic returns to the fishery, reducing growth overfishing, and providing a buffer against recruitment overfishing.

DATE: Comments must be received on or before August 14, 1986.

ADDRESS: Comments should be sent to Donald W. Geagan, Southeast Region, National Marine Fisheries Service, 9450 Koger Boulevard, St. Petersburg, Florida 33702.

FOR FURTHER INFORMATION CONTACT: Donald W. Geagan, 813–893–3722.

SUPPLEMENTARY INFORMATION: The Atlantic swordfish fishery is regulated under the Fishery Management Plan for Atlantic Swordfish (FMP) and its final regulations (50 CFR Part 630).

An international Stock Assessment Workshop held in April 1986 concluded that Western North Atlantic swordfish are being harvested at a level well beyond the level that would allow maximum production. In addition, the size of fish being taken by the fishery is well below the size that would produce maximum yield. With the recent expansion of the fishery into the Caribbean, the major spawning area, there is also increasing concern for the integrity of the adult spawning stock.

In consideration of these conclusions, the scientific subpanel of the Swordfish Working Panel recommended that, at a minimum, the adult population not be allowed to decline below present levels. Further, it was recognized that, reducing effort by approximately 60 percent would increase long-term yield by as much as 25 percent annually. Unless fishing effort is reduced, growth overfishing will continue, maximum

long-term yields will never be realized, and the possibility of recruitment overfishing will continue to increase.

The primary mechanism in the FMP for regulating the domestic fishery is the VSC The VSC operates by closing areas at times when small swordfish are most concentrated. The duration of these closures is determined by the number of small swordfish harvested the previous year (1985) relative to the number harvested in 1980 (base year).

Five areas are recognized for management purposes and separate closures claculated for each, as specified under § 630.21(a). These are: (1) New England and Mid-Atlantic; (2) South Atlantic to the Florida-Georgia border; (3) Florida East Coast; (4) Gulf of Mexico; and (5) Caribbean.

As provided for in the FMP and implementing regulations at § 630.21(c). the Swordfish Working Panel met on May 14-16, 1986, and evaluated the preliminary report of the Stock Assessment Workshop and the data from which the VSC is calculated. Starting dates for the VSC were approved by the Chairman of each of the five Council Swordfish Committees. Subsequently, each Council considered the recommendations of the Working Panel and its Committee Chairman, and provided its recommendations on VSC starting and ending dates to the South Atlantic Council as follows:

	Start	1	End	Num- ber of days
New England and Mid- Atlantic.	Oct. 1	Oct	13	13
South Atlantic	Oct. 1	Oct.	14	14
Florida East Coast				
Gulf of Mexico				
Caribbean	Sept. 1	Nov.	30	91

The duration of closures was determined in conformance with the procedures specified in the approved portion of the FMP and its implementing regulations.

The VSC is expected to reduce the catch of small swordfish by 3,866 fish, from 40,091 (1985 level) to 36,225 (1980 level) (9.64 percent). This reduction is considered minimal relative to the necessary reductions suggested by the 1986 stock assessment. However, this is the only action available that will immediately reduce or stabilize fishing effort. Thus, the South Atlantic Council, in concurrence with the New England, Mid-Atlantic, Gulf of Mexico, and Caribbean Councils recommends that the specified closures be implemented.

Other Matters

This action is taken under the authority of 50 CFR 630.21, and is taken in compliance with Executive Order 12291. This action is covered by the regulatory impact review and regulatory flexibility analysis for the FMP which concluded that the authorizing regulations could have a significant economic impact on a substantial number of small entities.

(18 U.S.C. 1801 et seq.)

List of Subjects in 50 CFR Part 630

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: July 25, 1986.

William G. Gordon,

Assistant Administrator for Fisheries, National Marine Fisheries Service. [FR Doc. 86-17210 Filed 7-28-86; 12:43 pm] BILLING CODE 3510-22-M

Notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forms Under Review by Office of Management and Budget

July 25, 1986.

The Department of Agriculture has submitted to OMB for review the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35) since the last list was published. This list is grouped into new proposals, revisions, extensions, or reinstatements. Each entry contains the following information:

(1) Agency proposing the information collection; (2) Title of the information collection; (3) Form number(s), if applicable; (4) How often the information is requested; (5) Who will be required or asked to report; (6) An estimate of the number of responses; (7) An estimate of the total number of hours needed to provide the information; (8) An indication of whether section 3504(h) of Pub. L. 96–511 applies; (9) Name and telephone number of the agency contact person.

Questions about the items in the listing should be directed to the agency person named at the end of each entry. Copies of the proposed forms and supporting documents may be obtained from: Department Clearance Officer, USDA, OIRM, Room 404–W Admin. Bldg., Washington, DC 20250, [202] 447–2118.

Comments on any of the items listed should be submitted directly to: Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attn: Desk Officer for USDA.

If you anticipate commenting on a submission but find that preparation time will prevent you from doing so promptly, you should advise the OMB Desk Officer of your intent as early as possible.

Federal Register

Vol. 51, No. 148

Wednesday, July 30, 1986

Extension

 Agriculural Stabilization and Conservation Service
 7 CFR Part 752 WBP Regulations ASCS-691, ASCS-817 Annually

Individuals or households; Farms; 6,200 responses; 1,185 hours; not applicable under 3504(h)

Charles Sims, (202) 447-7443

 Farmers Home Administration
 7 CFR 1980-C, Guaranteed Emergency Livestock Loans

On occasion

Businesses or other for-profit; 27 responses; 26 hours; not applicable under 3504(h)

Jack Holston, (202) 382-9738

· Forest Service

Disposal of Mineral Materials (36 CFR 228 Subpart C)

FS-2800-9, R1-FS-2850-1 On occasion; Annually

Individuals or households; State or local governments; Businesses or other forprofit; Federal agencies or employees; Non-profit institutions; Small businesses or organizations; 3,776 responses; 9,440 hours; not applicable under 3504(h)

Norman Day (703) 235-9784

 National Agricultural Statistics Service

Monthly Cold Storage Report Monthly

Businesses or other for-profit; 13,600 responses; 5,813 hours; not applicable under 3504(h)

Lee Sandberg, (202) 447-6820

 National Agricultural Statistics Service

Field Crop Objective Yield Survey Annually

End of Season

Farms; 17.495 responses; 5,326 hours; not applicable under 3504(h) Lee Sandberg (202) 447-6820.

New

Economic Reserch Service
U.S. Rural Land Transfer Survey
Once

Individuals or households: State or local government; 28,000 responses; 9,660 hours; not applicable under 3504(h)

T. Alexander Majchrowicz, (703) 786– 1425.

Revision

 Cooperative State Research Service Grant Application Kit OGPS-661, 662, 663, and 55 Annually

Individuals or households; State or local governments; Businesses or other forprofit; Federal agencies or employees; Non-profit institutions; 3,206 responses; 17,633 hours; not applicable under 3504(h)

Pat Shelton, (202) 475-5050

 Farmers Home Administration
 7 CFR 1942-A, Community Facility Loans

440-11, -24, 442-2, -3, -7, -20, -21, -22, -28, -30, -46, 1942-8, -9,-19, -47

Recordkeeping; On occasion; Quarterly, Annually

State or local governments; Businesses or other for-profit; Non-profit institutions; Small businesses or organizations; 104,748 responses; 232,085 hours; not applicable under 3504(h)

Jack Holston, (202) 382-9736.

Jane A. Benoit,

Departmental Clearance Officer. [FR Doc. 86–17122 Filed 7–29–86; 8:45 am] BILLING CODE 3410-01-M

Office of the Secretary

State of Alabama Agricultural and Conservation Development Commission Program; Determination of Primary Purpose of Program Payments for Consideration as Excluded From Income under Section 126 of the Internal Revenue Code of 1954

AGENCY: Office of the Secretary, USDA.
ACTION: Notice of determination.

SUMMARY: The Secretary of Agriculture has determined that cost-share payments made to individuals under the Alabama Agricultural and Conservation Development Commission Program are made primarily for the purpose of soil and water conservation, protecting or restoring the environment, improving forests, or providing a habitat for wildlife. This determination, which is made in accordance with section 126(b) of the Internal Revenue Code of 1954, as amended, and the provisions of 7 CFR Part 14, permits recipients of these payments to exclude them from gross income for federal income tax purposes if certain other conditions are met.

FOR FURTHER INFORMATION CONTACT: Chairman, Alabama Agricultural and Conservation Development Commission, 1445 Federal Drive, P.O. Box 3336, Montgomery, Alabama 36109, or Director, Land Treatment Program Division, Soil Conservation Service, USDA, P.O. Box 2890, Washington, DC 20013, (202) 382–1870.

SUPPLEMENTARY INFORMATION:

Section 126 of the International Revenue Code of 1954, as added by the Revenue Act of 1978 and amended by the Technical Correction Act of 1979, 26 U.S.C. 126, provides that certain payments made under state programs may be eligible for exclusion from gross income if certain determinations are made. The Secretarty of Agriculture must determine whether payments made under a state program, as described in section 126(a)(10), are "made primarily for the purpose of conserving soil and water resources, protecting or restoring the environment, improving forests, or providing a habitat for wildlife." In making this determination, the Secretary of Agriculture must evaluate each program according to criteria set forth in 7 CFR Part 14. Before there may be an exclusion, the Secretary of the Treasury must determine that the payments made to a person under these conservation programs do not substantially increase the annual income derived from the property benefited by the payments.

Alabama Law Act No. 85-123, Code of Alabama, Title 9, section 9-8A-1 et seq., established the Alabama Agricultural and Conservation Development Commission, to administer and coordinate the Alabama Agricultural and Conservation Development Commission Program as provided for in the act. Cost-share grants of money are derived from appropriations made to the commission by the Alabama legislature to encourage and finance soil conservation, water quality improvement, and improved forestry practices in the state. The act further authorizes the commission to set qualifications and criteria for recipients of cost-share grants and to enter into contracts with others for the organization and servicing of such costshare grants. The state Soil and Water Conservation Committee is authorized to implement the commission's costshare program through the state's 67 local soil and water conservation districts.

Section 2 of the act, Code of Alabama, Title 9, § 9-8A-2, sets forth the purpose of the legislation: ". . . to provide for the restoration and conservation of the soil resources of this state, to provide for the improvement of water used in agriculture, and for the control and prevention of soil erosion and for the

prevention of floodwater and sediment damages, and for the establishment or improvement of stands of forest trees, all of which will preserve natural resources, control floods, prevent impairment of dams and reservoirs, preserve wildlife, protect the tax base, protect public lands and promote the health, safety and public welfare of the citizens of the state."

Procedural Matters

The authorizing legislation, regulations, and operating procedures for the Agricultural and Conservation Development Commission Program of the state of Alabama have been carefully examined using the criteria set forth in 7 CFR Part 14. The Department has concluded that the payments made under this cost-share program are made to provide financial assistance to eligible persons in carrying out soil and water conservation measures, protecting or restoring the environment, improving forests, or providing wildlife habitat.

An Alabama Agricultural and Conservation Development Commission Program, "Primary Purpose Determination for Federal Tax Purposes," Record of Decision, has been prepared and is available upon request from the Chairman, Alabama Agricultural and Conservation Development Commission, 1445 Federal Drive, P.O. Box 3336, Montgomery, Alabama 36109, or Director, Land Treatment Program Division, Soil Conservation Service, USDA, P.O. Box 2890, Washington, D.C. 20013, (202A) 382–1870.

Determination

It is hereby determined in accordance with Section 126(b) of the Internal Revenue Code of 1954, as amended, and 7 CFR Part 14 that all cost-share payments made for conservation practices under Alabama Agricultural and Conservation Development Commission Program are for the following, as applicable: soil and water conservation, protecting or restoring the environment, improving forests, or providing wildlife habitat. Subject to further determination by the Secretary of the Treasury, this determination permits payment recipients to exclude from gross income for federal income tax purposes, all or part of such payments made under the Alabama Agricultural Conservation Development Commission Program after June 4, 1985.

Signed at Washington, DC, on July 24, 1986. Richard E. Lyng, Secretary.

[FR Doc. 86-17049 Filed 7-29-86: 8:45 am] BILLING CODE 3410-01-M

Office of International Cooperation and Development

Intent To Amend a Cooperative Agreement; Iowa State University

AGENCY: Office of International Cooperation and Development.

ACTION: Notice of Intent to Amend a Cooperative Agreement.

Activity: The Office of International Cooperation and Development (OICD) intends to amend a Cooperative Agreement with Iowa State University to develop technologies for the fortification of food products with vitamin A an to transfer the technologies to less developed countries.

Authority: Section 1458 of the National Agricultural Research, Extension and Teaching Policy Act of 1977, as amended (7 U.S.C. 3291), and the Food Security Act of 1985 (Pub. L. 99–198).

OICD announces the availability of funds for fiscal year 1987 (FY 1987) to amend an agreement with the Agricultural and Home Economics Experiment Station, Iowa State University, to provide additional funding support and extend the duration of the support until 30 September 1988. The amendment will enable the University to continue activities to assist developing countries in alleviating Vitamin A deficiencies which the University, in cooperation with OICD, started on 1 August 1985. Assistance for these activities will be provided only to Iowa State University.

Based on the above, this is not a formal request for application. An estimated \$102,000 will be available in FY 1987 to support this work. It is anticipated that the amendment to the agreement will be funded over a 24-month budget period.

Information may be obtained from: Nancy J. Croft, Contracting Officer, Management Services Branch, Office of International Cooperation and Development, U.S. Department of Agriculture (58–319R–5–034, Amendment 1).

Dated: July 25, 1986.
Allen Wilder,
Contracting Officer.
[FR Doc. 86–17033 Filed 7–29–86; 8:45 am]
BILLING CODE 3410–DP-M

Food and Nutrition Service

National Advisory Council on Maternal, Infant and Fetal Nutrition; Meeting

Pursuant to the Federal Advisory Committee Act Pub. L. 92–463), announcement is made of the following Council meeting:

Date and Time: August 19-21, 1986; 9:00 a.m.

Place: Food and Nutrition Service, 3101 Park Center Drive, 4th Floor, Alexandria, Virginia 22302.

Purpose of Meeting: The Council will continue its study of the Special Supplemental Food Program for Women, Infants and Children (WIC) and the Commodity Supplemental Food Program (CSFP).

Agenda: The agenda items will include the following issues: formulation of recommendations for the Council's 1986 report to the President and Congress; and general program operations. Recommendations for the report will address administrative and legislative changes for the WIC and CSF Programs.

Meetings of the Council are open to the public. Members of the public may participate, as time permits. Persons wishing additional information about this meeting should contact Lynn Jordan. Supplemental Food Programs Division, Food and Nutrition Service, U.S. Department of Agriculture, Alexandria, Virginia 22302. Telephone: [703] 756– 3730.

Dated: July 21, 1986.

Robert E. Leard.

Administrator.

[FR Doc. 86-17053 Filed 7-29-86; 8:45 am]

BILLING CODE 3410-30-M

Soil Conservation Service

Bear River Watershed Protection Plan, MI

AGENCY: Soil Conservation Service, U.S. Department of Agriculture.

ACTION: Notice of finding of no significant impact.

SUMMARY: Pursuant to section 102(2)[C] of the National Environmmental Policy Act of 1969; the Council on Environmental Quality Guidelines. (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact

statement is not being prepared for the Bear River Watershed, Charlevoix and Emmet Counties, Michigan.

FOR FURTHER INFORMATION CONTACT:

Mr. Homer R. Hilner, State Conservationist, Soil Conservation Service, 1405 South Harrison Road, East Lansing, Michigan 48823, telephone 517– 337–6702.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally-assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. A contact has been made with the State Historical Preservation Officer and concludes that it will have no effect on any cultural resources either eligible for or listed on the National Register of Historic Places. The State Archaeologist will be contacted if any land disturbance associated with this project and archaeological sites, features, or materials are encountered during actual construction. As a result of these findings, Mr. Homer R. Hilner, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

This project concerns a plan for the installation and treatment of practices for watershed protection. These practices will include: conservation tillage, critical area treatment, grassed waterways, stripcropping, diversions, sediment basins, wildlife plantings and water quality improvement measures. Total financial assistance cost is estimated to be \$1,300,700: \$716,600 Pub. L.-566 funds, and \$584,100 local funds.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency. The basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Homer R. Hilner. The FONSI has been sent to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address.

Implementation of the proposal will not be initiated until 30 days after the date of this publication in the Federal Register.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.901—Resource Conservation and Development—and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials.) Dated: July 23, 1986.

Homer R. Hilner,

State Conservationist.

[FR Doc. 86–17023 Filed 7–29–86; 8:45 am]

BILLING CODE 3410–16–M

DEPARTMENT OF COMMERCE

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration Title: Gulf and South Atlantic Fishery Management Plan

Form Number: Agency—N/A: OMB— 0648–0136

Type of Request: Extension of the expiration date of a currently approved collection

Burden: 9 respondents; 3 reporting hours
Needs and Uses: The Coral and Coral
Reefs Fishery Management Plan
provides protection to the coral and
coral reefs in the Gulf of Mexico and
South Atlantic. The data collected is
used by the National Marine Fishery
Service and the South Atlantic and
Gulf Councils in monitoring quotas,
changes in fishing effort, and the
disposition of the harvested species.

Affected Public: State or local government; businesses or other forprofit institutions; non-profit institutions; small businesses or organizations

Frequency: Annually Respondent's Obligation: Mandatory OMB Desk Officer: Sheri Fox, 395–3785.

Copies of the above information collection proposal can be obtained by calling or writing DOC Clearance Officer, Edward Michals, (202) 377–4217, Department of Commerce, Room 6622, 14th and Constitution Avenue, NW. Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Sheri Fox, OMB Desk Officer, Room 3235, New Executive Office Building, Washington, DC 20503.

Dated: July 25, 1986.

Edward Michals,

Departmental Clearance Officer, Information Management Division, Office of Information Resources Management.

[FR Doc. 86-17112 Filed 7-29-86; 8:45 am] BILLING CODE 35:0-CW-M

Foreign-Trade Zones Board

[Docket No. 25-86]

Foreign-Trade Zone 66—Wilmington, NC; Application for Expansion

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the North Carolina Department of Commerce, grantee of Foreign-Trade Zone 66, requesting authority to expand the zone to include the entire Port of Wilmington terminal complex in Wilmington, North Carolina, within the Wilmington Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on July 18, 1986.

On April 14, 1981, the Board authorized the North Carolina Department of Commerce to establish a foreign-trade zone in Wilmington (Board Order 174, 46 FR 22919, 4/22/81). The project currently covers 36 acres within the Port of Wilmington terminal

complex.

The application requests the designation of the entire 390-acre terminal complex as a zone to provide flexibility in meeting the growing demand for zone services. Parcels within this area would be activated as needed after Customs approval.

In accordance with the Board's regulations, an examiners committee has been appointed to investigate the application and report to the Board. The committee consists of: Joseph Lowry, (Chairman), Foreign-Trade Zones Staff, U.S. Dept. of Commerce, Washington, D.C. 20230; Howard Cooperman, Deputy Assistant Regional Commissioner, U.S. Customs Service, Southeast Region, 99 S.E. 5th St., Miami, FL 33131; and Colonel Wayne A. Hanson, District Engineer, U.S. Army Engineer District Wilmington, P.O. Box 1890, Wilmington, NC 28402.

Comments concerning the proposed expansion are invited in writing from interested parties. They should be addressed to the Board's Executive Secretary at the address below and postmarked on or before August 29, 1986.

A copy of the application is available for public inspection at each of the following locations:

District Director's Office, U.S. Customs Service, 2094 Polk St., Wilmington, NC 28401

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Rm 1529, 14th & Pennsylvania Ave., NW., Washington, DC 20230 Dated: July 24, 1986.

Dennis Puccinelli,

Acting Executive Secretary.

[FR Doc. 86–17076 Filed 7–29–86; 8:45 am]

International Trade Administration

Cornell University; Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 86–179. Applicant: Cornell University, Ithaca, NY 14853. Instrument: Laser Interferometer System. Manufacturer: Transelek Enr., Canada. Intended Use: See notice at 51 FR 16729.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument provides a frequency response to 40 megahertz and resolution to 0.02 nanometers. The National Bureau of Standards advises in its memorandum dated June 18, 1986 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials) Frank W. Creel,

Director, Statutory Import Programs Staff. [FR Doc. 88–17077 Filed 7–29–86; 8:45 am] BILLING CODE 3510-DS-M

Consolidated Decision on Applications for Duty-Free Entry of Mass Spectrometers

This is a decision consolidated pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 1523. U.S. Department of Commerce, 14th & Constitution Avenue, NW., Washington, DC

Docket Number: 86–175. Applicant: University of Washington, Seattle, WA 98195. Intended use: See notice at 51 FR 15820.

Docket Number: 86–191. Applicant: Oregon State University, Corvallis, OR 97331. Intended Use: See notice at 51 FR 17383.

Instrument: Gas Isotope Ratio Mass Spectrometer, Model 251 with Accessories. Manufacturer: Finnigan MAT Corp., West Germany. Advice Submitted By: National Bureau of Standards: June 23, 1986.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as each is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument can analyze stable isotope composition of less than 5.0 microliters of carbon dioxide with a guaranteed internal precision of 0.006 %. The National Bureau of Standards advises in its respectively cited memoranda that (1) this capability is pertinent to each applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value for the intended use of each instrument.

We know of no other instrument or apparatus being manufactured in the United States which is of equivalent scientific value to the foreign instruments.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials) Frank W. Creel.

Director, Statutory Import Programs Staff.
[FR Doc. 86-17078 Filed 7-29-86; 8:45 am]

[C-211-602]

Extension of the Deadline Date for the Final Countervalling Duty
Determination and Rescheduling of the Public Hearing; Operators for Jalousie and Awning Windows From El Salvador

AGENCY: Import Administration, International Trade Administration, Commerce.

ACTION: Notice.

SUMMARY: Based upon the request of petitioners, the Anderson Corporation and the Caribbean Die Casting Corporation, we are extending the deadline date for the final determination in the countervailing duty investigation of operators for jalousie and awning windows from El Salvador to correspond to the date of the final determination in the antidumping duty investigation of the same product pursuant to section 705(a)(1) of the Tariff Act of 1930, as amended by section 606 of the Trade and Tariff At of 1984 (Pub. L. 98-573). In accordance with Article 5, paragraph 3 of the Agreement on Interpretation and Application of Articles VI, XVI and XXIII of the General Agreement on Tariffs and Trade (the Subsidies Code), the Department will terminate the suspension of liquidation in the countervailing duty investigation 4 months after the date of publication of the preliminary determination in this case. In addition, we are rescheduling the public hearing.

EFFECTIVE DATE: July 30, 1986.

SUPPLEMENTARY INFORMATION:

FOR FURTHER INFORMATION CONTACT:
Barbara Tillman or Steven Morrison,
Office of Investigations, Import
Administration, International Trade
Administration, U.S. Department of
Commerce, 14th Street and Constitution
Avenue NW., Washington, DC. 20230;
telephone: [202] 377–2438 or 377–1248.

Case History

On March 19, 1986, we received antidumping and countervailing duty petitions filed by the Anderson Corporation and the Caribbean Die Casting Corporation on operators for jalousie and awning windows from El Salvador. In compliance with the filing requirements of § 353.36 of our regulations (19 CFR 353.36), the antidumping petition alleged that imports of operations for jalousie awning windows from El Salvador are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Tariff Act of 1930, as amended (the Act) and that these imports materially injure. or threaten material injury to, a U.S. industry.

We found that the petition contained sufficient grounds upon which to initiate an antidumping duty investigation, and on April 8, 1986, we initiated such investigation (51 FR 13039). The preliminary determination in this antidumping investigation will be made on or before April 26, 1986.

In compliance with the filing requirements of § 353.26 of our regulations (19 CFR 355.26), the countervailing duty petition alleged that manufacturers, producers, or exporters in El Salvador of operators for jalousie

and awning windows directly or indirectly receive benefits which constitute subsidies within the meaning of section 701 of the Act, and that these imports materially injure, or threaten material injury to, a U.S. industry.

We found that the petition contained sufficient grounds upon which to initiate a countervailing duty investigation, and on April 8, 1986, we initiated such investigation (51 FR 12633). On May 5, 1986, the ITC preliminary determined that there is a reasonable indication that imports of operators of jalousie and awning windows from El Salvador threaten material injury to a U.S. industry (51 FR 17683). On June 12, 1986, we issued a preliminary affirmative determination in the countervailing duty investigation on operators for jalousie and awning windows from El Salvador (51 FR 22099).

On June 24, 1986, petitioners filed a request for extension of the deadline date for the final determination in the countervailing duty investigation to correspond with the date of the final determination in the antidumping investigation.

Section 705(a)(1) of the Tariff Act of 1930, as amended by section 606 of the Trade and Tariff Act of 1984, provides that when a contervailing duty investigation is "initiated simultaneously with an (antidumping) investigation . . . which involves imports of the same class or kind of merchandise from the same or other countries, the administering authority, if requested by the petitioner, shall extend the date of the final determination (in the countervailing duty investigation) to the date of the final determination" in the antidumping investigation (19 U.S.C. 1671d(a)(1)). Pursuant to this provision, we are granting an extension of the deadline date for the final determination in the countervailing duty investigation of operators for jalousie and awning windows from El Salvador to November 10, 1986, the current deadline for the final determination in the antidumping duty investigation.

Article 5, paragraph 3 of the Agreement on Interpretation and Application of Articles VI, XVI, and XXIII of the General Agreement on Tariffs and Trade ("Subsidies Code") provides that provisional measures (i.e., suspension of liquidation) may not be imposed on another Code Signatory for a period longer than four months. While El Salvador is not a signatory to the Subsidies Code, a reciprocal trade agreement exists between the United States and El Salvador which requires unconditional most-favored-nation treatment with respect to all rules and formalities connected with the

importation and exportation of merchandise (50 Stat. 1564; Executive Agreement Series 101, Article X. February 19, 1937). We consider this bilateral agreement to require that El Salvador be given the same advantages and privileges as any Signatory to the Subsidies Code, Therefore, the Department will direct the U.S. Customs Service to terminate the suspension of liquidation in the countervailing duty investigation on October 18, 1986, which is 4 months from the date of publication of the preliminary determination in this case. No cash deposits or bonds for potential countervailing duties will be required for merchandise which enters after October 18, 1986. The suspension of liquidation will not be resumed unless and until the Department publishes a countervailing duty order in this case. We will also direct the U.S. Customs Service to hold any entries suspended prior to October 18, 1986, until the conclusion of this investigation.

In addition, due to the extension of the final determination in the countervailing duty investigation, we are rescheduling the date of the public hearing, originally set for July 28, 1986. This hearing will now be held on August 18, 1986 at 10:00 a.m. at the U.S. Department of Commerce, Room 3708, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Individuals who wish to participate in the hearing must submit a request to the Deputy Assistant Secretary for Import Administration, Room B-099, at the above address within 15 days of the publication of this notice.

Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; (3) the reason for attending; and (4) a list of the issues to be discussed. In addition, at least 10 copies of prehearing briefs must be submitted to the Deputy Assistant Secretary at Room B-099 by August 11, 1986. Oral presentations will be limited to issues raised in the briefs.

In accordance with 19 CFR 355.33(d) and 19 CFR 355.34, written views will be considered if received within 10 days after the hearing transcript is available.

This notice is published pursuant to section 705(a)(1) of the Tariff Act of 1930, as amended by section 606 of the Trade and Tariff Act of 1984 (Pub. L. 98–573).

Gilbert B. Kaplan,

Deputy Assistant Secretary for Import Administration.

July 24, 1986.

[FR Doc. 86-17113 Filed 7-29-86; 8:45 am] BILLING CODE 3510-DS-M

Export Privilege; Archie Zickler

In the matter of Archie Zickler, Vice President/Purchasing Roy M. Huffington, Inc. First International Plaza, 1100 Louisiana Avenue, Suite 5500, Houston, Texas 77002, Respondent.

Order

The Office of Export Enforcement, International Trade Administration, United States Department of Commerce (Department), having determined to initiate an administrative proceeding against Archie Zickler (Zickler) pursuant to section 13(c) of the Export Administration Act of 1979 (50 U.S.C. app. 2401-2420 (1982), as amended by the Export Administration Amendments Act of 1985, Pub. L. 99-64, 99 Stat. 120 (July 12, 1985)) and Part 388 of the **Export Administration Regulations** (currently codified at 15 CFR Parts 368-399 (1986)) (the Regulations), based on allegations that Zickler violated §§387.4, 387.5 and 387.6 of the Regulations in that, on or about July 1, 1983, Zickler exported or caused to be exported, from the United States to Indonesia, one central processing unit without the validated export license which Zickler knew, or had reason to know, was required by §372.1(b) the Regulations and that Zickler indirectly falsified a material fact to the Department in connection with that export;

The Department and Zickler having entered into a Consent Agreement whereby the parties have agreed to settle this matter: (1) By Zickler's paying the Department a civil penalty of \$10,000; and (2) by denying Zickler's export privileges for a period of sixty days following the date of entry of this

Order; and

The terms of the Consent Agreement having been approved by me;

It is therefore ordered, first, that a civil penalty in the amount of \$10,000 is assessed against Zickler. Payment of the civil penalty will be made to the Department within 20 days of the service of this Order on Zickler, in the manner specified in the attached

instructions.

Second, for a period of sixty days starting on July 28, 1986, Zickler is denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction involving commodities or technical data exported or to be exported from the United States in whole or in part, or that are otherwise subject to the Regulations. Without limiting the generality of the foregoing, participation, either in the United States or abroad, shall include, directly or indirectly, participation in any manner or capacity: (i) As a party or as a

representative of a party to any export license application submitted to the Department, (ii) in preparing or filing with the Department any export license application or request for reexport authorization, or any document to be submitted therein, (iii) in obtaining from the Department or using any validated or general export license or other export control document, (iv) in carrying on negotiations with respect to, or in receiving, ordering, buying, selling, delivering, storing, using, or disposing of any commodities or technical data, in whole or in part, exported or to be exported from the United States, and (v) in financing, forwarding, transporting, or other servicing of such commodities or technical data. Such denial of export privileges shall extend only to those commodities and technical data which are subject to the Act and the Regulations.

Third, after notice and opportunity for comment, such denial may be made applicable to any person, firm, corporation, or business organization with which Zickler is now or hereafter may be related by affiliation, ownership, control, position of responsibility, or other connection in the conduct of trade or related services.

Fourth, during the period of denial of export privileges set forth above, no person, firm, corporation, partnership or other business organization, whether in the United States or elsewhere, without prior disclosure to and specific authorization from the Office of Export Licensing shall, with respect to U.S.origin commodities and technical data, do any of the following acts, directly or indirectly, or carry on negotiations with respect thereto, in any manner or capacity, on behalf of or in any asssociation with Zickler or whereby Zickler may obtain any benefit therefrom or have any interest or participation therein, directly or indirectly: (a) Apply for, obtain, transfer, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to any export, reexport, transshipment, or diversion of any commodity or technical data exported in whole or in part, or to be exported by, to, or for Zickler; or (b) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate in any export, reexport, transshipment, or diversion of any commodity or technical data exported or to be exported from the United States.

Fifth, that the proposed Charging Letter, the Consent Agreement and this Order shall be made available for public inspection.

This order is effective immediately. Entered this 25th day of July 1986.

Theodore W. Wu,

Deputy Assistant Secretary for Export Enforcement.

IFR Doc. 86-17114 Filed 7-29-86 8:45 am] BILLING CODE 3510-DS-M

National Oceanic and Atmospheric Administration

Marine Mammals; Issuance of Permit to Northwest and Alaska Fisheries Center, National Marine Fisheries Service (P77#19)

On June 3, 1986, notice was published in the Federal Register (51 FR 1982) that an application had been filed by the Northwest and Alaska Fisheries Center, National Marine Fisheries Service (NMFS), 7600 Sand Point Way, NE., Seattle, Washington 98115 to take North Pacific fur seals (Callorhinus ursinus) for scientific research on islands in the Bering Sea and the Channel Islands of

Notice is hereby given that on July 16, 1986, as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 USC 1381-1407), and the Fur Seal Act (16 USC 1151-1187), the National Marine fisheries Service issued a Permit for the above taking, subject to certain conditions set forth therein.

The Permit is available for review by interested persons in the following offices:

Office of Protected Species and Habitat Conservation, F/M4, NMFS, Room 805, 1825 Connecticut Ave., NW., Washington, DC;

Director, Northwest Region, NMFS, 7600 Sand Point Way, NE., Seattle, Washington 98115;

Director, Alaska Region, NMFS, 709 West 9th Street, Federal Building, Juneau, Alaska 99802; and

Director, Southwest Region, NMFS, 300 South Ferry Street, Terminal Island, California 90731.

Dated: July 22, 1986.

Henry R. Beasley,

Director, Office of International Fisheries, National Marine Fisheries Service.

[FR Doc. 86-17029 Filed 7-29-86; 8:45 am] BILLING CODE 3510-22-M

Marine Mammals, Proposed Permit Modification; Dr. Richard H. Lambersten (P277)

Notice is hereby given that Dr. Richard H. Lambertsen, Department of Physiological Sciences, Box J-144, JHMHC, University of Florida,

Gainesville, Florida 32610, has requested a modification to Permit No. 336, issued on May 19, 1981 (46 FR 28694), under the authority of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216), the Endangered Species Act of 1973 [16 U.S.C. 1531-1543) and the regulations governing endangered species permits (50 CFR Parts 217-222).

The Permit Holder is requesting to import specimen materials of fin (Balaenoptera physalus), sei (Balaenoptera borealis) and minke (Balaenoptera acutorostrata) whales from Iceland. The whales will be taken by the Government of Iceland under its research permit, for research purposes.

Concurrent with the publication of this notice in the Federal Register, the Secretary of Commerce is forwarding copies of this modification request to the Marine Mammal Commission and the Committee of Scientific Advisors.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, Washington, DC 20235, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular modification request would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries.

All statements and opinions contained in this notice are summaries of those of the Applicant and not necessarily reflect the views of the National Marine Fisheries Service.

Documents submitted in connection with the above modification are available for review by interested persons in the following offices:

Office of Protected Species and Habitat Conservation, National Marine Fisheries Service, 1825 Connecticut Avenue, N.W., Room 805, Washington,

Regional Director, Northeast Region, National Marine Fisheries Service, 14 Elm St., Fed. Bldg., Gloucester, MA

01930; and

Regional Director, Southeast Region, National Marine Fisheries Service. 9450 Koger Boulevard, St. Petersburg, FL 33702.

Henry R. Beasley,

Director, Office of International Fisheries, National Marine Fisheries Service.

[FR Doc. 86-17030 Filed 7-29-86; 8:45 am] BILLING CODE 3510-22-M

Marine Mammals; Application for Permit; Zoo Negara (P383)

Notice is hereby given that an Applicant has applied in due form for a Permit to take marine mammals as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216).

1. Applicant:

a. Name. Zoo Negara.

b. Address. Ulu Kelang, 68000 Ampang, Selangor, Malaysia.

2. Type of Permit: Public Display. 3. Name and Number of Marine Mammals:

California sea lions (Zalophus californianus) 5.

South American sea lions (Otaria

flavescens) 2.

4. Type of Activity: Export, The animals will be transferred from the San Diego Zoo, no take from the wild is involved.

5. Period of Activity: Two (2) years. As a request for a permit to take living marine mammals to be maintained in areas outside the jurisdiction of the United States, this application has been submitted in accordance with National Marine Fisheries Service policy concerning such applications (40 FR 11619, March 12, 1975). In this regard, no application will be considered unless:

(a) It is submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, through the appropriate agency of the foreign

government;

(b) It includes:

i. A certification from such appropriate government agency verfiying the information set forth in the application;

ii. A certification from such government agency that the laws and regulations of the government involved permit enforcement of the terms of the conditions of the permit, and that the government will enforce such terms;

iii. A statement that the government concerned will afford comity to a National Marine Fisheries Service decision to amend, suspend or revoke a

In accordance with the above cited policy, the certification and statements of the Veterinary Headquarters, Ministry of Agriculture Malaysia have been found appropriate and sufficient to allow consideration of this permit application.

The arrangements and facilities for transporting and maintaining the marine mammals requested in the above described application have been inspected by a licensed veterinarian,

who has certified that such arrangements and facilities are adequate to provide for the well-being of the marine mammals involved.

Concurrent with the publication of this notice in the Federal Register, the Secretary of Commerce is forwarding copies of this applicatin to the Marine Mammal Commission and the Committee of Scientific Advisors.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, Washington, DC 20235, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries.

All statements and opinions contained in this application are summaries of those of the Applicant and do not necessarily reflect the views of the National Marine Fisheries Service.

Documents submitted in connection with the above application are available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 1825 Connecticut Avenue, NW., Washington, DC; and Director, Southwest Region, National Marine Fisheries Service, 300 South Ferry Street, Terminal Island, California.

Dated: July 24, 1986. Henry R. Beasley, Director, Office of International Fisheries, National Marine Fisheries Service. [FR Doc. 86-17125 Filed 7-29-86; 8:45 am] BILLING CODE 3510-22-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE **AGREEMENTS**

Extending Coverage of the Hong Kong **Export Visa Requirement to Include Textiles and Textile Products of** Vegetable Fibers (Other Than Cotton), Silk Blends, and Man-Made Fiber Textile Products in Category 670

July 25, 1986.

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, has issued the directive published below to the Commissioner of Customs to be effective on August 1. 1986. For further information contact

Ann Fields, International Trade Specialist, Office of Textile and Apparel, U.S. Department of Commerce, (202)377–4212.

Background

The Governments of the United States and Hong Kong have reached agreement to extend coverage of the existing export visa requirement to include textiles and textile products of vegetable fibers, other than cotton, such as ramie, linen, jute, abaca, etc., and silk blends in Categories 800 through 899, and luggage, handbags, and flat goods in Category 670, produced or manufactured in Hong Kong and exported to the United States. This coverage is in addition to the previously established coverage of cotton, wool and man-made fiber textiles and textile products. The visa itself and the officials authorized by the Government of Hong Kong to issue visas are not being changed at this time. Accordingly, in the letter published below the Chairman of CITA directs the Commissioner of Customs, effective on August 1, 1986, to amend the directive of January 14, 1983 to extend coverage to the aforementioned products, exported on and after August 1, 1986. A listing of the new categories with brief descriptions of each is published as an enclosure to that letter.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the Federal Register on July 29, 1986.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements. July 25, 1986.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20029

Dear Mr. Commissioner: This letter further amends, but does not cancel, the directive of January 14, 1983 from the Chairman of the Committee for the Implementation of Textile Agreements which directed you to prohibit entry and withdrawal from warehouse for consumption in the United States of cotton, wool and man-made fiber textiles and textile products in Categories 300–369, 400–469, and 600–669, produced or manufactured in Hong Kong and exported on and after January 1, 1983, for which the Government of Hong Kong had not issued an appropriate export visa.

Effective on August 1, 1986, the directive of January 14, 1983 is hereby amended to require that textiles and textile products of vegetable fibers, other than cotton, such as ramie, linen, jute, abaca, etc., and silk blends in Categories 800 through 899 and Category 670 (luggage, handbags, and flat goods) also be visaed if exported on and after August 1, 1986. A listing of the new categories with brief descriptions of each is enclosed. Part

Categories 845(1) and 845(2) and 846(1) and 846(2) shall be treated in accordance with the instructions set forth in the directive of December 29, 1982 concerning correct subcategory designations and parts of categories to be shown on visas.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the Federal Register on July 29, 1986.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Brief Description	Silk blends and other vegeta- ble fibers
Non-MFA Appoarel	
Gloves and mittens	831
Hosiery	832
M&B Sult-type jackets	833
M&B other coats and jackets	834
W,G&I coats and jackets	835
Dresses	836
Knit shirts, blouses, and tops	838
Not knit shirts and blouses	840
Skirts	842
M&B suits	843
W,G&I suits	844
Sweaters of vegetable fibers	845
Sweaters of silk	846
Trousers, slacks, and shorts	847
Robes and dressing gowns	850
Pajamas and other nighwear	851
Underwear	852
Nickwear	858
Other apparel	859
Non-MFA Nonapparel	
Yarn and thread	800
Fabrics	810
Towels	863
Luggage	870
Handbags and flatgoods	871
Other made-ups	899

[FR Doc. 86-17131 Filed 7-29-86; 8:45 am] BILLING CODE 3510-DR-N

Extending Coverage of the Taiwan Export Visa Requirement To Include Textiles and Textile Products of Vegetable Fibers (Other Than Cotton) and Silk Blends

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, has issued the directive published below to the Commissioner of Customs to be effective on August 1, 1986. For further information contact Kathy Davis, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377–4212.

Background

The American Institute in Taiwan (AIT) and the Coordination Council for North American Affairs (CCNAA) have agreed to extend coverage of the existing export visa requirement to include textiles and textile products of vegetable fibers, other than cotton, such as ramie, linen, jute, abaca, etc., and silk blends in Categories 800 through 899. produced or manufactured in Taiwan and exported to the United States. This coverage is in addition to the previously established coverage of cotton, wool and man-made fiber textiles and textile products. The visa itself and the official authorized by the CCNAA to issue visas are not being changed at this time. Accordingly, in the letter published below the Chairman of CITA directs the Commissioner of Customs, effective on August 1, 1986, to amend the directive of September 27, 1972 to extend coverage to the aforementioned products, exported on and after August 1, 1986. A listing of the new categories with brief descriptions of each is published as an enclosure to that letter.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on July 29, 1986.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements. July 25, 1986.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20029

Dear Mr. Commissioner: This letter further amends, but does not cancel, the directive of September 27, 1972 from the Chairman of the Committee for the Implementation of Textile Agreements which directed you to prohibit entry and withdrawal from warehouse for consumption in the United States of cotton, wool and man-made fiber textiles and textile products, produced or manufactured in Taiwan for which the authorities in Taiwan had not issued an appropriate export visa.

Effective on August 1, 1986, the directive of September 27, 1972 is hereby further amended to require that textiles and textile products of vegetable fibers, other than cotton, such as ramie, linen, jute, abaca, etc., and silk blends in Categories 300 through 899 also be visaed if exported on and after August 1, 1986. A listing of the new categories with brief descriptions of each is enclosed.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the Federal Register on July 29, 1986.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements:

Brief description	Silk blends and other vegeta- ble fibers
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Non-MFA Apparel

Gloves and mittens	831
Hosiery	832
M&B suit-type jackets	833
M&B other coats and jackets	834
W,G&I coats and jackets	835
Dresses	836
Knit shirts, blouses, and tops	838
Not knit shirts and blouses	840
Skirts	842
M&B suits	843
W.G&I suits	B44
Sweaters of vegetable fibers	845
Sweaters of silk	846
Trousers, slacks, and shorts	847
Robes and dressing gowns	850
Pajamas and other nightwear	851
Underwear	852
Neckwear	858
Other apparel	859

Non-MFA Non-apparel

Yam and thread	800
Fabrics	810
Towels	863
Luggage	870
Handbags and flatgoods	871
Other made-ups	899

[FR Doc. 86-17132 Filed 7-29-86; 8:45 am]

CONSUMER PRODUCT SAFETY COMMISSION

Proposed Collection of Information; Survey on Residential Swimming Pools

AGENCY: Consumer Product Safety

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1981 (44 U.S.C. Chapter 35), the Consumer Product Safety Commission (CPSC) has submitted to the Office of Management and Budget a request for approval, through September 30, 1987, of a proposed collection of information in the form of a survey of households having swimming pools.

Drownings in residential swimming pools have consistently ranked as one of the leading causes of death among children under age five. The CPSC has established a priority project for fiscal year 1987 to determine what action, if any, should be taken to reduce these deaths and the serious injuries occurring to small children in residential pools.

The Commission has planned a study to measure factors associated with residential pools in which a child has drowned or almost drowned and to measure the same factors for residential pools in the general population in the same geographic areas. The first part of this study is already under way in eight selected U.S. counties where CPSC investigators are focusing on factors including fencing, gate locks, pool alarms, pool covers, and knowledge of cardio-pulmonary resuscitation.

The second part of the study, concerned with the same factors for the general population of residential pools in the same areas, requires the use of a survey. Using a mail screener questionnaire, a consumer panel will identify a representative sample of approximately 200 pool owners. A telephone survey of the owners will follow.

The data from the two parts of the study will be compared, with the results used by the Commission to determine its policy on residential swimming pools. Among the options will be (a) working cooperatively with the industry on the design of pools and safety devices, (b) informing and educating the public about pool safety and rescue practices, and (c) identifying factors that could be mandated by state or local governments to reduce the drowning risk.

Additional Details About the Proposed Collection of Information

Agency address: Consumer Product Safety Commission, 1111 18th Street, NW., Washington, DC 20207.

Title of information collection: Survey on residential swimming pools.

Type of request: New plan. Frequency of collection: One screening questionnaire and one telephone interview.

General description of respondents: Potential owners of residential swimming pools.

Estimated number of respondents: 10,000 for screening questionnaire and 200 for telephone survey.

Estimated number of hours for all respondents: 217.

Comments: Comments on this request for approval of a proposed collection of information should be addressed to Marina Gatti, Desk Officer, Office of Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, telephone (202) 395–7340. Copies of this request for approval of the proposed collection of information are available from Francine Shacter, Office of Budget, Program Planning, and Evaluation, Consumer Projuct Safety Commission, Washington, DC 20207; telephone (301) 492–6529.

This is not a proposal to which 44 U.S.C. 3504(h) is applicable.

Dated: July 25, 1986.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 86-17083 Filed 7-29-86; 8:45 am] BILLING CODE 6355-01-M

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Intent To Prepare a Draft Environmental Impact Statement (DEIS) for a Proposed Regulatory Permit to the Santa Fe Pacific Realty Corporation To Construct Hotels on San Franciso Bay in Emeryville, CA

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent to prepare a draft environmental impact statement (DEIS).

SUMMARY: 1. The Santa Fe Pacific Realty Corporation seeks a Department of the Army permit to construct two hotels, up to 185 feet in height with a total of 600 rooms, on the San Francisco shoreline in Emeryville, California. The proposed action would include the removal of approximately two acres of San Francisco Bay fill, and the filling in of approximately two acres of San Francisco Bay mudflats. Additional lands would be dedicated to public open space and wildlife preserve.

2. Reasonable alternatives that have been identified to date are:

a. A 300–450 room business travel suite hotel with similar Bay cutting and

filling.

b. A 300-450 room business travel suite hotel with no Bay cutting or filling.

c. Residential structures with no Bay cutting or filling.

d. Relocation of proposed hotels to other property in Emeryville already owned by the Santa Fe Co.

e. Acquisition of a different site.

f. Alternative uses of the proposed site, such as public facilities, or park/ open space.

g. No project.

 a. Public Notice No. 1640947 about the permit request was issued May 2, 1986. Fifty-six comments have been received, from Federal, State, and local agencies and from organizations and individuals.

 b. The following significant issues have been identified for analysis in the DEIS:

Alternative Site Consideration Clean Water Act Complicance Construction Period Impacts Endangered Species—possibly
California clapper rail, salt marsh
harvest mouse, California brown
pelican

Habitat Resources—effects on salt marsh, mudflats; wintering birds, waterfowl, residents shorebirds, shellfish

Public Use of Shoreline Seismic Safety

Seismic Safety
Shoreline Park and Trail Proposals
Structural Effects of Hotel Buildings—as
physicial barriers, sun reflection, wind
deflection, shadows, night lighting
interference with roosting

Tidal Pool—effect of construction of proposed pool on water quality

Traffic

View Obstruction, aesthetics
Water Current Alteration—changes in
tidal flows, sediment deposition,
storm sewer outfall flowage

Water Quality—turbidity and toxic substance release from excavation of existing fill; increased urban run-off

c. The applicant has been requested to prepare an alternative site analysis to comply with 40 CFR 230 404(b)(1).

d. The applicant has been requested to prepare a biological assessment for submission to the U.S. Fish and Wildlife Service in compliance with 50 CFR 402.

4.a. In order to further clarify issues and identify potential new ones that should be addressed in the DEIS, a scoping meeting will be held. Notice of the meeting is being widely distributed to facilitate public comment. The meeting will be held on Wednesday, August 20, 1936 in the Emeryville, City Hall, 2449 Powell St. Registration will begin at 6:30 pm; the agenda is: 7:00-7:15 pm. presentation of project by Santa Fe Pacific Realty Co.; 7:15-8:30 Federal, State and Regional agency plans and concerns; 8:30-9:15 Municipal plans and concerns; 9:15-9:30 clarifications, comments by Santa Fe Pacific Realty Co.; 9:30-11:00 pm public organizations and individuals. If additional time is needed to accomodate all those wishing to speak, the meeting will reconvene in the same place on Saturday, August 23 1986 at 9:00 am.

 b. Submission of written comments is encouraged, and may be sent to the address given below up to September 3, 1986.

5. The DEIS will be prepared jointly with an Environmental Impact Report being prepared by the City of Emeryville. It is estimated that the joint Draft EIR-EIS will be available to the public in the spring of 1987.

ADDRESS: Questions about the proposed action and DEIS can be answered by: Dr. Richard Lerner, Environmental Branch; U.S. Army Corps of Engineers;

211 Main Street; San Francisco, CA 94105-1905. (415) 974-0440.

Dated: July 1986

Andrew M. Perkins, Jr.,

Lieutenant Colonel, Corps of Engineers, District Engineer.

[FR Doc. 86-17079 Filed 7-29-86; 8:45 am] BILLING CODE 3710-FS-M

Defense Intelligence Agency

Membership of the Defense Intelligence Agency Performance Review Committee; Correction

AGENCY: Defense Intelligence Agency (DIA).

ACTION: Correction of notice.

SUMMARY: The following is a correction to a notice printed in the Federal Register on Wednesday, July 16, 1986 (51 FR 25728):

DELETE: Dr Wynfred Joshua, Defense Intelligence Officer—European and Soviet Political/Military Affairs

SUBSTITUTE: Mr. Geoffrey H. Langsam, Assistant Deputy Director for Imagery Exploitation Linda M. Lawson,

Alternate OSD Federal Register Liaison Officer, Department of Defense. July 25, 1983.

[FR Doc. 86-17058 Filed 7-29-86; 8:45 am] BILLING CODE 3810-01-M

Defense Logistics Agency

Hazardous Material Management in the New Jersey Area; Intent To Prepare Environmental Impact Statement

AGENCY: Defense Reutilization and Marketing Service (DRMS), Defense Logistics Agency (DLA), Department of Defense (DoD).

ACTION: Notice.

SUMMARY: In accordance with 40 CFR 1501.7, the Defense Logistics Agency issues this Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) for the management of hazardous material and waste generated by DoD activities in the New Jersey area. Interested parties are invited to attend scoping meetings to be held during the period 25–27 August 1986 at locations listed below.

FOR FURTHER INFORMATION CONTACT:

Dr. Herold Balbach, U.S. Army
Construction Engineering Research
Laboratory—Environmental Division
[USA CERL-EN], P.O. Box 4005,
Champaign, IL 61820-1305.

Telephone: 1-800-523-2973 (Toll Free Within the State of New Jersey) FTS: 958-7251

Commercial: 217-373-7251 or 217-352-6511, Ext. 251

SUPPLEMENTARY INFORMATION:

Purpose

The DRMS, a field operating command of the Defense Logistics Agency (DLA), is charged with the acceptance and the contracting for disposal of hazardous wastes and hazardous materials generated on the installations of all branches of the Department of Defense (DoD). To further this mission, and to comply with current requirements of the Resource Conservation and Recovery Act (RCRA) and other Federal and state regulations which may apply to the temporary storage of hazardous waste in New Jersey, the DRMS proposes to evaluate all reasonable alternative methods and physical sites for managing such wastes. An EIS will be prepared to identify and evaluate the potential for significant impacts to the biophysical and socioeconomic environments which may result from completing the alternative or alternatives available to DRMS.

This EIS will evaluate the storage and management alternatives for hazardous material and waste generated from DoD industrial-type activities. Examples include used degreasing solvents, used paint thinner, drained motor oil, and unusable automoblie and truck batteries. All ultimate disposal of these items is by licensed (civilian) hazardous waste disposal facilities. No permanent disposal of these wastes on DoD lands is contemplated or will be considered in this EIS. The following categories of items are not, and will not be considered for disposal under this action: Radiological wastes; toxicological, biological and lethal chemical warfare wastes; municipal-type refuse; municipal-type sewage sludge; refuse from mining, dredging and demolition; explosives and munitions; and unique nonrecurring wastes generated by research and development activities.

The following eight New Jersey DoD installations are affected by this action:

- -U.S. Army Training Center, Fort Dix
- -McGuire Air Force Base
- Naval Air Engineering Center, Lakehurst
- -Naval Air Propulsion Center, Trenton
- —Naval Weapons Station Earle, Colts Neck
- -U.S. Army Communication Electronics Command, Ft. Monmouth
- -Military Ocean Terminal, Bayonne
- —U.S. Army Research and Development Center, Picatinny Arsenal, Dover

Potential Alternatives

Potential alternatives include the following:

 Upgrading existing facilities at any or all installations to meet RCRA and other requirements for conforming shortterm hazardous waste container storage.

(2) Construction and operation of a regional, short-term conforming storage building or buildings at any or all of the DoD installations under consideration in New Jersey.

(3) Construction and operation of a regional, short-term storage building or buildings at a location or locations within reasonable transport distances of a number of hazardous waste generating DoD installlations.

(4) The development and choice of new or unforseen alternatives which might also attain the goals mentioned above are not precluded.

It is anticipated that certain of these alternatives will be demonstrated to be inappropriate or physically impossible to implement at certain locations; therefore, detailed examination of such alternatives will be terminated when inrrevocable unsuitability can be demonstrated.

Scoping

Interested Federal, state and local agencies as well as interested private organizations and parties are invited to participate in the EIS process. The public will be involved to the maximum extent possible in these activities and is encouraged to participate in the planning process. Written information or comments from such agencies, organizations or individuals are welcome at any time during the process. Telephone inquiries may be made to the numbers given above.

Public scoping meetings, at which comments are concerns about relevant issues to be addressed in the EIS preparation may be expressed, are scheduled for the period 25–27 August 1986 at the following locations:

(a) Tinton Falls Borough Hall, 556 Tinton Avenue, Tinton Falls, NJ 07724— August 25, 1986 between 7:00 and 9:30 p.m.

(b) Manchester Municipal Building, 1 Colonial Drive, Lakehurst, NJ 98733— August 26, 1986 between 7:00 and 9:30 p.m.

(c) New Hanover Township Municipal Building, Hockomick Road and Main Street, Cookstown, NJ 08511—August 27, 1986 between 7:00 and 9:30 p.m.

The Draft EIS is expected to be available for public review and comment in approximately 8 to 10 months.

An official public comment period regarding the completed Draft EIS will begin at the time the Draft EIS is filed, and will conclude approximately 45 days following. If necessary, meetings will be scheduled for a time during this period to receive public comment and testimony. Formal notice of this period and of any concurrent meetings will be made at the time the Draft EIS is filed.

Interested parties wishing copies of the Draft EIS may submit their name and address to the person indicated above or may leave their name and address at one of the scoping meetings.

Dated: July 25, 1986.

Rockwood S. Dunham,

Colonel, USA, Staff Director, Installation Services and Environmental Protection. [FR Doc. 86–17048 Filed 7–29–86; 8:45 am] BILLING CODE 3520-01-M

DEPARTMENT OF ENERGY

Office of Assistant Secretary for International Affairs and Energy Emergencies

Atomic Energy Agreements; Proposed Subsequent Arrangement; Canada

Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C 2160) notice is hereby given of a proposed "subsequent arrangement" under the Agreement for Cooperation between the Government of the United States of America and the Government of Canada concerning Civil Uses of Atomic Energy, as amended.

The subsequent arrangement to be carried out under the above-mentioned agreement involves approval of the following sale:

Contract Number S-CA-390, for the sale of 63.5805 grams of natural uranium to the Key Lake Mining Corp., Saskatchewan, Canada, for use as standard reference material.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

For the Department of Energy.

Dated: July 25, 1986.

David B. Waller,

Assistant Secretary for International Affairs and Energy Emergencies.

[FR Doc. 86-17133 Filed 7-29-86; 8:45 am]

Atomic Agreements; Proposed Subsequent Arrangement; European Atomic Energy Community

Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160) notice is hereby given of a proposed "subsequent arrangement" under the Additional Agreement for Cooperation between the Government of the United States of America and the European Atomic Energy Community (EURATOM) concerning Peaceful Uses of Atomic Energy, as amended.

The subsequent arrangement to be carried out under the above-mentioned agreement involves approval of the following sale:

Contract Number S-EU-891, for the sale of 100 milligrams of uranium-236 to the United Kingdom Atomic Energy Authority, Harwell, England, for use as a calibration standard and certification of analytical method reliability.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice. For the Department of Energy.

Dated: July 25, 1986.

David B. Waller.

Assistant Secretary for International Affairs and Energy Emergencies.

[FR Doc. 86-17134 Filed 7-29-86; 8:45 am]
BILLING CODE 6450-01-M

Atomic Agreements; Proposed Subsequent Arrangement; European Atomic Energy Community

Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160) notice is hereby given of a proposed "subsequent arrangement" under the Additional Agreement for Cooperation between the Government of the United States of America and the European Atomic Energy Community (EURATOM) concerning Peaceful Uses of Atomic Energy as amended.

The subsequent arrangement to be carried out under the above-mentioned agreement involves approval of the following sale:

Contract Number S-EU-893, for the sale of 0.02 grams of plutonium-244 to the Central Bureau for Nuclear Measurements, Geel, Belgium, for use as standard reference material.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

For the Department of Energy. Dated: July 25, 1986.

David B. Waller,

Assistant Secretary for International Affairs and Energy Emergencies.

[FR Doc. 86-17135 Filed 7-29-86; 8:45 am]

BILLING CODE 6450-01-M

Bonneville Power Administration

Policy for Public Involvement

AGENCY: Bonneville Power Administration (BPA), DOE. ACTION: Notice of Final Policy (BPA File No.: PI-1).

SUMMARY: BPA is adopting a Policy for Public Involvement which affirms the public involvement practices in which it cuurently engages. A Notice of Intent and Proposed Policy with Request for Comment was issued on March 12, 1986. The Policy for Public Involvement revises the Procedure for Public Participation in Major Regional Power Policy Formulation. The policy applies to public involvement for major regional power policies and other BPA actions. It contains general objectives, required procedures, and optional activities for informing and involving the public. The Policy for Public Involvement will help the public to anticipate and participate in BPA's decisionmaking processes and will assist BPA in consistently providing appropriate opportunities for interaction with the public

Responsible Official: Donna L. Geiger, Public Involvement Manager, is the official responsible for developing the

DATE: This policy is effective immediately.

ADDRESSES: Additional copies of the final policy may be obtained from Donna L. Geiger, Public Involvement Manager, Bonneville Power Administration, P.O. Box 12999 Portland, Oregon 97212. The Official Record for the development of the policy may be viewed at the Public Involvement Office, Bonneville Power Administration, 1002 NE. Holladay Street, Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Teresa M. Cunningham, Public Involvement staff, at the above address or the following telephone numbers (voice/TTY): 503-230-3478 from

Portland; 800-452-8429 from Oregon outside of Portland; or 800-547-6048 from California, Idaho, Montana, Nevada, Utah, Washington, and Wyoming, Information may also be obtained from:

Mr. George E. Gwinnutt, Lower Columbia Area Manager, Suite 288, 1500 Plaza Building, 1500 NE. Irving Street, Portland, Oregon 97232, 503-230-4551.

Mr. Ladd Sutton, Eugene District Manager, U.S. Federal Building, Room 206, 211 East Seventh Avenue, Eugene, Oregon 97401, 503-687-6959.

Mr. Terence G. Esvelt, Puget Sound Area Manager, Room 250, 415 First Avenue North. Seattle, Washington 98109, 206-442-4130.

Mr. Wayne R. Lee, Upper Columbia Area Manager, U.S. Courthouse, Room 581, West 920 Riverside Avenue, Spokane, Washington 99201, 509-456-2518.

Mr. George E. Eskridge, Montana District Manager, 800 Kensington, Missoula, Montana 59801, 406-329-3060.

Mr. Ronald K. Rodewald, Wenatchee District Manager, P.O. Box 741, Wenatchee, Washington 93801, 509-662-4377

Mr. Thomas V. Wagenhoffer, Snake River Area Manager, West 101 Poplar, Walla Walla, Washington 99362, 509-522-6225.

Mr. Robert N. Laffel, Idaho Falls District Manager, 531 Lomax Street, Idaho Falls, Idaho 83401, 208-523-2706.

Mr. Frederic D. Rettenmund, Boise District Manager, 550 West Fort Street, Room 376, Boise, Idaho, 83724, 208-334-9137

SUPPLEMENTARY INFORMATION:

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Section V. Public Involvement Procedures for Major Regional Power Policies Section VI. Public Involvement for Other **BPA** Actions

Section VII. Relationship to National Environmental Policy Act (NEPA) III. Explanation of Policy Provisions

I. Background

The Pacific Northwest Electric Power Planning and Conservation Act of 1980 (Pacific Northwest Power Act) directs BPA to conduct a thorough program to inform and involve the public of the Pacific Northwest in those electric power and conservation issues which concern it. In addition, the National Environmental Policy Act of 1969, as amended, requires that BPA seek and consider public views on environmental impacts of its actions. Other Federal statutes and Executive Orders may also require BPA to conduct some type of

public involvement depending upon the circumstances. BPA has moved to meet these mandates through a wide range of activities designed to explain BPA activities and elicit public recommendations.

It is BPA's intent to continue to provide appropriate opportunities for the public to participate in BPA's decisionmaking processes. This commitment to public involvement responds to the fundamental right of all citizens to participate in the decisions of their government. BPA has found that the best interests of both public policy and prudent business practice have been served by directly involving BPA's constituencies in its decisionmaking

A. Current BPA Public Involvement Activities. BPA's public involvement activities span a wide range of issues, publics, and processes. In each, the goal is to offer vehicles for public participation that are appropriate to the resources of the interested public, the complexity of the subject, and the impacts of the action involved.

BPA has provided public involvement opportunities in the development of a number of major regional power policies. Examples of such policies are: BPA's Billing Credits Policy, Customer Service Policy, Transmission Policy, and the Fish and Wildlife Consultation Procedures.

BPA has also involved the public in many other important issues. These actions include: determinations on significant regional issues; annual planning activities; development of generic contracts; program development; research and development projects; and the planning, construction, and maintenance of transmission facilities. Some specific examples of these activities are BPA's Direct Service Industries Options Study, Resource Strategy, Load Forecast, Long-Term Conservation Contracts, Model Conservation Standards Implementation Program, and Fall River-Lower Valley Reinforcement Project. Many different public involvement techniques have been used in these actions. Some involved symposiums or town hall meetings. Others used roundtable discussions, workshops, and technical work groups to reach specific publics. In some situations, a more informal approach was appropriate and techniques such as open houses and contracts with landowners were used.

In addition to these public involvement activities, BPA conducts regular consultations with its customers; State, local, and tribal governments: public utility commissions; interest

groups; and others. These discussions are informal and may include issues which are in some stage of public involvement at the time of the consultation. As such, these exchanges may be an important part of the public involvement efforts on specific issues.

B. Other Procedures for Special Activities. The Pacific Northwest Power Act requires very specific public involvement procedures for the acquisition of major power resources [sec. 6(c)] and the establishment of rates [sec. 7(i)]. It also requires consultation with certain publics concerned with fish and wildlife issues [sec. 4(h)(11)(B)]. No administrative procedures have been established yet for the acquisition of major power resources. BPA has further defined the procedures for establishing rates in its Procedures Governing Bonneville Power Administration Rate Hearings (51 FR 7611, March 5, 1986) and has used these procedures in subsequent rate cases. BPA has published procedures (50 FR 23173, May 31, 1985) for consulting with fish and wildlife agencies, Indian tribes, and hydroelectric project operators on fish and wildlife issues in the management and operation of Federal hydroelectric facilities. All of these procedures are referenced in the Policy for Public Involvement.

C. Development of Policy for Public Involvement. Subsequent to adoption of the Procedure for Public Participation in Major Regional Power Policy Formulation (46 FR 26368, May 12, 1981), BPA greatly expanded both the number and kinds of opportunities available for the public to participate in its actions. BPA also identified several ways in which that procedure could be strengthened. As a result, on March 12, 1986 (51 FR 8624), BPA published a Notice of Intent and Proposed Policy with Request for Comment. The Proposed Policy for Public Involvement was a revision of the Procedure for Public Participation in Major Regional Power Policy Formulation.

The comment period on the proposed policy extended from March 12 through April 18, 1986, and was subsequently reopened on request to receive comments at a meeting with leaders of public interest groups on April 22, 1986. Twenty written comments and 12 oral comments were received on the proposed policy from 29 organizations

and individuals.

A Staff Evaluation of the Official
Record, which summarizes and
evaluates the comments, and contains
staff recommendations was prepared. In
addition, a Record of Decision was
written which describes the
Administrator's decisions on each issue

and the reasons for those decisions. Both of these documents are part of the Official Record for the development of the Policy for Public Involvement. This record may be viewed at BPA's Public Involvement office.

II. Text of Policy for Public Involvement

Section I. Purpose

The purpose of this policy is to affirm the Bonneville Power Administration's commitment to insure widespread public involvement in the formulation of regional power policies and other appropriate actions. The procedures described in the policy will clarify for the public how it can expect to be informed of actions under consideration by BPA and to take part in the deliberations leading to BPA's decisions. The procedures will also guide BPA in consistently providing appropriate opportunities for interaction with the public on such matters.

Section II. Objectives

Through this policy, BPA intends to provide the public with the fullest information practicable on BPA policy and program development, to provide early and effective opportunities for the public to express its opinions and concerns, and to consider the views and information presented by the public prior to reaching decisions.

The procedures contained in this policy necessarily reflect the flexibility reserved for the Administrator by law. By preserving this flexibility, it is not the intent of the policy to limit unnecessarily the extent of public involvement, but rather to preserve the Administrator's discretion to act quickly when necessary and to conduct routine business without cumbersome procedural requirements.

Section III. Scope

This policy applies to major regional power policies as described in Section V and to other BPA actions as described in Section VI.

- A. The policy does not apply to:
- 1. Interpretive rulemaking;
- Rules of internal agency organization, procedure, or practice;
- 3. Policies for which another exclusive procedure is required by law or regulation, or for which the Administrator has established alternative procedures that supersede this policy.
- a. BPA ratemaking, Pacific Northwest Electric Power Planning and Conservation Act, Pub. L. 96–501, sec. 7(i). This exclusive procedure is set forth in the Procedures Governing Bonneville

Power Administration Rate Hearings, (51 FR 7611, March 5, 1986.)

b. Acquisition of a major resource,
Pacific Northwest Electric Power
Planning and Conservation Act, Pub. L.
96–501, sec. 6(c). This statute describes a
process that includes public notice and
comment, development of a record, and
review by the Northwest Power
Planning Council and appropriate
committees of Congress. BPA has not
yet developed specific procedures to
implement this provision.

B. This policy may apply in addition to procedures that have been established for special activities, such as the Fish and Wildlife Consultation Procedures (50 FR 23173, May 31, 1985). These procedures describe how BPA will consult with Columbia River Basin fish and wildlife agencies, Indian tribes, and hydroelectric project operators as it fulfills its responsibilities in the management and operation of the Federal Columbia River Power System hydroelectric facilities. The consultation procedures provide for combining and coordinating the Fish and Wildlife Consultation Procedures and the public involvement procedures for developing major regional power policies.

Section IV. Definition

A. Administrator. The Bonneville Power Administrator.

B. Customer. A person or entity having a direct relationship with BPA as the result of contractual arrangements for the purchase, exchange, transfer, assignment, or sale of electric power and energy, related services, or transmission capability to, with, or from BPA.

C. Decision Document. A document which describes the decisions made on a major regional power policy, the information considered, and the reasons for the decisions.

D. Interested Person. Any person, group, or entity with an interest in the proposed action or decision.

E. Major Regional Power Policy. An agency statement of future effect and general applicability designed to implement, limit, or prescribe policy which the Administrator identifies as involving major regional power issues. The term major regional power policy does not include the development and execution of particular agreements, contracts, or other instruments between BPA and its customers, except for those generic agreements, contracts, or other instruments which the Administrator identified as establishing major regional power policy.

F. Public. Affected or interested persons; organizations; or groups;

including but not limited to BPA customers; officials of local, State, and Indian tribal governments; and officials of other Federal agencies.

G. Public Comment Forum. A meeting for which public notice is given and during which oral comments are presented to BPA.

H. Public Information Program. A program using a variety of techniques, designed to inform the public of BPA actions, policies, or decisions.

I. Public Involvement. Informal as well as systematic opportunities for members of the public to know about and express their opinions on possible BPA decisions or actions. The term "public involvement" is considered to be synonymous with "public participation," and is the term normally used within

J. Public Involvement Program. A program of activities, using a variety of techniques, to inform the public of proposed BPA actions or decisions and to provide opportunities for the public to express opinions and make recommendations which BPA considers before taking actions or making a

K. Public Meeting. Opportunities for BPA to exchange information and views with the public in person. These meetings may involve a few or many persons and take such forms as briefings, workshops, symposiums, or roundtable discussions.

L. Public Record. Except as otherwise expressly provided by law, the compiled and indexed records which document the development of a major regional power policy.

Section V. Public Involvement Procedures for Major Regional Power Policies

A. Decision to Formulate a Policy and Notice of Intent. When the Administrator decides to formulate a major regional power policy, the Administrator shall publish a notice of intent to formulate the policy. The purpose of the notice of intent is to offer to interested persons the opportunity to make recommendations on the policy to be developed. Notice shall include the followings:

1. The subject of the proposed policy;

2. An explanation of the need for and the probable effect of the policy with a statement of available information on these issues:

3. The legal authority under which the policy is being developed;

4. An indication of the extent to which other existing policies might be affected by the development of the new policy;

5. A request for written recommendations for BPA's use in formulating or revising the policy;

6. The time limit for the receipt of such

recommendations; and

7. The name, address, and telephone number of the BPA official who will receive them.

The Administrator may combine the notice of intent with either the notice of policy alternatives or the notice of

- proposed policy.

 B. Notice of Policy Alternatives. Where determined appropriate, the Administrator may issue a notice describing and requesting comment on possible alternatives for a proposed policy. Information obtained in response to the notice of intent and other information available to BPA may be used to identify these alternatives. Public comment on the alternatives will assist BPA in preparing a proposed policy. The notice of policy alternatives shall incude:
 - 1. The text of the policy alternatives;

2. The dates, times, and locations of any scheduled public meetings;

3. Information on procedures by which interested persons may participate in any public meetings;

4. A request for written comments on

the policy alternatives;

5. Any time limits for receipt of such comments;

6. The name, address, and telephone number of the BPA officical(s) to contact for further information; and

7. Any other information considered

necessary.

C. Notice of Proposed Policy. After the period for receipt of recommendations stated in the notice of intent or for comments on the notice of policy alternatives, the Administrator shall publish a notice of the proposed policy. The notice shall include:

 The text of the proposed policy: 2. An indication of the probable extent to which other existing policies may be affected by the proposed policy; 3. The dates, times and locations of

scheduled public comment forums and/

or public meetings;

4. Information on procedures by which interested persons may participate in public comment forums or meetings;

5. A request for written comments on the Policy;

6. Any time limits for receipt of such

- 7. The name, address, and telephone number of the BPA official(s) to contact for further information; and
- 8. Any other information considered
- D. Public Comment Forums. One or more public comment forums shall be scheduled on the proposed policy so

that interested persons may present their views on the proposed policy in person.

The Administrator shall determine the number, dates, locations, and time of day of such forums. Notice of the forums shall be published either as part of the notice of proposed policy or in a separate notice. The notice shall include:

1. The name, subject, and purpose of the policy:

2. The date(s), time(s), and place(s) for the forums;

- 3. Information on any available material which discusses the need for the policy and effects which the policy may have:
- 4. The time period for receipt of comments;
- 5. The names, addresses, and telephone numbers of BPA officials from whom additional information can be obtained; and

6. Other material which is considered

necessary.

BPA shall offer interested persons the opportunity for oral presentation of views, data, and arguments. Persons who wish to speak at public comment forums should, before the forum, notify the BPA Public Involvement Manager or the Area or District Manager of the locality in which the forum will be held. This will permit preparation of a tentative schedule of participants. Time limitations may be established for oral presentations to assure that all interested persons who desire to speak will have an opportunity to do so. Interested persons with similar views, data, and arguments may be required to consolidate their comments.

A verbatim transcript of these comments is ordinarily prepared and included in the record of the hearing. When a transcript is not prepared, a detailed summary of the hearing is made instead. During the period in which a major regional power policy is being developed, transcripts or summaries of public comment forums shall be available for review at the Area or District office in the locality where the forum is held. Copies of the transcripts or summaries of forums shall also be available for review in BPA's Public Involvement office. The transcript or summary of the forum, as well as any written comments, documents, or exhibits submitted at the forum, shall be placed in the Public Record.

E. Public Meetings. The Administrator may determine the need for public meetings in addition to the public forum(s) specified above.

The subjects and purposes, dates, times, and locations of the meetings shall be announced. Meeting notices may also describe the format of the meeting, and the nature of the participation opportunities which may be offered.

These meetings may serve a number of purposes, including:

1. Providing information regarding the proposed policy or alternatives:

 Permitting a detailed public review and exchange of information regarding technical data or methodology;

 Providing an opportunity for public comment at interim stages in the decisionmaking process; and

4. Other purposes determined by the Administrator to be consistent with this policy for Public Involvement.

A transcript is ordinarily not prepared for these meetings. A summary may be prepared, and may be mailed to meeting participants with an invitation to comment upon the summary or submit additional publics comments, documents, or exhibits. The meeting summary, if prepared, and any subsequent comments, documents, and exhibits shall be placed in the Public Record.

F. Time Allowed for Public
Recommendations or Comment and for
Notice of Public Comment Forums and
Meetings. Whenever practicable, the
Administrator shall allow at least 30
days for the public to submit written
recommendations in response to a
notice of intent and to offer comments
on a notice of policy alternatives and
notice of proposed policy.

Whenever practicable, the Administrator shall allow at least 15 days advance notice of public comment forums and public meetings.

G. Decision Document. Following the comment period on a notice of proposed policy, a decision document shall be completed. The decision document shall be signed by the Administrator and made a part of the publics record. The decision document shall include:

A description of the proposed action;

A summary of the comments received on the proposed action;

 An evaluation of the proposed action and of other alternatives which have been recommended or identified by the public or BPA;

4. The Administrator's decision; and 5. A concise summary of the reasons

for the decision.

H. Notice of Final Policy. BPA shall publish a notice of any final policy. The policy shall become effective on the date of the publication of the notice unless otherwise specified.

I. Methods of Public Notification and Contact. Notices of intent, policy alternatives, proposed policy, public

comment forums, final policy, and, whenever practicable, notices of public meetings shall be published in the Federal Register, or elsewhere if so determined by the Administrator. In addition, the Administrator may send a written announcement to persons who have previously expressed an interest in the development of a major regional power policy, or to persons who, in the opinion of the Administrator, could reasonably be expected to have such an interest. The Administrator may also direct that an announcement be made in one or more general circulation newspapers in the BPA marketing area or through other effective means of publicity, as necessary or desirable.

In addition to written notice, the Administrator may initiate contact in person or by telephone with interested persons to inform them of opportunities to submit recommendations or comments.

J. Combination of Other Required Notices with Policy Notices. The Administrator may combine notices required by other laws and regulations with notices pertaining to major regional power policies.

K. Procedures for Expedited
Decisionmaking. 1. Any or all
procedures provided for in Section V do
not apply when the Administrator for
good cause finds that such notice and
public involvement are impracticable,
unnecessary, or contrary to the public
interest. The Administrator shall
incorporate such a finding and a brief
statement of the reasons for this finding
in any policy that is issued.

When such a finding is made, the Administrator may choose to adopt an interim policy specifying the period of time for which it will remain in effect.

In adopting an interim or a final policy, BPA shall be guided by the following principles:

a. Those procedures which the Administrator determines are practicable shall be completed.

b. To the extent practicable, alternative means of providing notice, informing the public, and providing opportunities for comment shall be used.

4. If an interim policy is adopted, the applicable procedures for major regional power policies shall be follwed in adopting the final policy.

L. Public Record. The records which document the development of a major regional power policy shall be compiled and indexed in a public record. The public record shall include the following:

1. All Federal Register or other notices provided for by these procedures;

The transcripts or summary prepared for the record of oral comments taken at public comment forums:

 Any transcripts or summaries prepared for the record of oral comment taken at public meetings;

 Written comments, data, and questions of public record and BPA's replies to these items;

5. The decision document; and

 Any other information that is determined by the Administrator to be relevant.

The public record shall be available for inspection or copying.

Section VI. Public Involvement for Other BPA Actions

A. Other BPA Actions for Which the Administrator May Conduct Public Involvement. The Administrator may determine that it is appropriate to conduct public involvement on other selected BPA actions. Such other actions may include:

 Formulation of policies which are not major regional power policies;

2. Planning activities and the development of plans related to areas such as energy conservation, renewable resources and other generating resources, fish and wildlife resources, and the transmission system;

3. Development and implementation of programs related to areas such as energy conservation, renewable and other generating resources, fish and wildlife resources, and the transmission system; and

 Other BPA actions related to major regional power issues.

B. Factors for Determining the Appropriate level of Public Involvement.

In determining the appropriate level of public involvement as well as the provision of notice and comment for other BPA actions, the Administrator may take into account pertinent factors such as:

1. The precedential nature of the action:

Whether and when public support is required for effective implementation of the contemplated action;

The effect on BPA and its customers:

The impact of the proposed action on the public;

The particular segment(s) of the public which can be expected to be interested in the action;

6. The level of public interest;
7. The time available for public involvement; and

8. The existence of previous or concurrent public involvement activities on similar actions.

Section VII. Relationship to National Environmental Policy Act (NEPA). To the maximum extent practicable, BPA shall implement the public involvement procedures described in this policy and the procedures required by the National Environmental Policy Act concurrently and in a complementary fashion. In order to minimize the impact on the public's resources, joint notices shall be issued and combined meetings shall be held whenever possible.

III. Explanation of Policy Provisions.

The policy contains nearly all of the procedural requirements which were contained in the Procedure for Public Participation in Major Regional Power Policy Formulation, with some modifications. In addition, the policy describes the types of other BPA actions for which the Administrator may conduct public involvement and the factors for determining the appropriate level and type of public involvement.

This section provides some background information on the meaning of the policy provisions. It also describes how the final policy revises the Procedure for Public Participation in Major Regional Power Policies and how the final policy differs from the proposed policy. A summary of the public comments received on the proposed policy and BPA's evaluation of the comments is contained in the Staff Evaluation of the Official Record, Proposed Policy for Public Involvement.

Section I. Purpose. The statement of purpose reflects the revised scope of the policy and describes the benefits of the policy to both the public and BPA. To clarify the actions covered by the policy, the proposed "commitment to insure widespread public involvement in the formulation of regional power policies" has been expanded in the final policy to include "and other appropriate actions".

include "and other appropriate actions."

Section II. Objectives. This is a new section which outlines how and why BPA intends to involve the public. The extent of and reasons for the flexibility retained by the Administrator are also described.

Section III. Scope. The scope of the policy has been revised to cover major regional power policies and other BPA actions. Alternative or joint coverage of actions by other procedures for public involvement is explained and the citation for the Procedures Governing Bonneville Power Administration Rate Adjustments has been updated. The language of the proposed policy has been changed slightly to include among the areas not covered by the policy, those policies for which a regulation establishes another exclusive procedure.

Section IV. Definitions. Terms which have a particular meaning for the policy are defined.

A. Administrator. [No change.]

B. Customer. In response to a comment on the proposed policy, "exchange" has been added to the list of identifying arrangements between BPA and its customers. This term was inadvertently omitted form the proposed policy.

C. Decision Document. This document combines and replaces the functions of the evaluation of the record and record of decision which were required by the previous procedure. The purpose of this new document is to streamline the presentation of this information by reducing the redundancy of the evaluation of the record and the record of decision. For ease of use, the final policy has been changed to include the description of the decision document's contents within Section V which pertains to major regional power policies.

D. Interested Person. [No change.]
E. Major Regional Power Policy. This definition has been expanded to cover generic agreements, contracts, or other instruments between BPA and its customers which, while not policies, nevertheless establish major regional power policy.

F. Public. This definition has been added to explain a basic term that is

used throughout the policy.

G. Public Comment Forum. This is a new definition which describes a particular kind of public meeting in which BPA receives public comments in person. The language of the proposed definition, which explained when a detailed summary of a public comment forum would be prepared instead of a verbatim transcript, has been moved to Section V of the policy.

H. Public Information Program. This definition has been added to differentiate a public information program from a public involvement program. In a public information program, the goal is to make information available to the public.

1. Public Involvement. This definition has been added to explain a term which

is basic to the policy.

J. Public Involvement Program. This is a new definition. In a public involvement program, information is provided to the public and opportunities are provided for the public to express its views and recommendations.

K. Public Meeting. This term has been added to describe a type of activity which BPA frequently uses in addition

to public comment forums.

L. Public Record. This new term is used for the agency record to avoid confusion with official records which are prepared for judicial review. As recommended in comments on the proposed policy, the description of the

contents of the public record have been revised to clarify that, when prepared for a the record, transcripts or summaries of public comments forums will always be included in the record as well as any transcripts or summaries of public meetings.

Section V. Public Involvement Procedures for Major Regional Power Policies.

A. Decision to Formulate a Policy and Notice of Intent. The Administrator decides which BPA actions are major regional power policies. While the policy does not include any specific critieria for making this determination, the Administrator typically considers the nature of the policy, the magnitude of its effect and the extent of the public sectors which will be impacted. Preliminary informal contacts by BPA with potential affected publics can assist the Administrator in the determination of which actions are major regional power policies.

The wording of this part has been adjusted to indicate that the decision and notice requirements apply only to major regional power policies. The description of alternate ways that notice may be given has been moved into subsection I., Methods of Public Notification and Contact.

The proposed content of the notice of intent to formulate a policy has been revised to specify that the explanation of "the need for and the probable effect of the policy" should also include "a statement of available information on these issues" as was required by the previous procedures. Also, the proposed policy's requirement that notice be published in the Federal Register or elsewhere has been moved to subsection I. Finally, the proposed language on combining the notice of intent with the notice of policy alternatives or with the notice of proposed policy has been incorporated in this section.

B. Notice of Policy Alternatives. This is a new part. In the development of certain major regional power policies, it may be appropriate for BPA to obtain helpful advice for the preparation of proposed policies by first seeking comments on alternatives for framing the policy. All policy development processes may not lend themselves to this step. The final policy revises the proposed policy by adding a description of what the notice of policy alternatives shall contain. The final policy also places the requirement that the notice of policy alternatives be published in the Federal Register or elsewhere in subsection I.

C. Notice of Proposed Policy. This part describes when a notice of proposed policy will be issued and the contents of such notice. In the final policy, the requirement that the notice of proposed policy be published in Federal Register or elsewhere has been moved to subsection I.

D. Public Comment Forum. This part describes all requirements for conducting public comment forums. The Procedure for Public Participation in Major Regional Power Policy Formulation has been revised by moving the language on other means of making notices available to subsection I., by modifiying the request for advance notice of participation in a comment forum, and by deleting the requirement that the responsible official must act as or appoint a chairman of the forum. BPA officials who are responsible for the development of a policy may still attend and chair public comment forums even though the section does not contain a specific reference to their role.

Information on the preparation of transcripts and detailed summaries that was contained in the proposed definition of the term has been moved to this subsection. The final policy also clarifies that local BPA offices will only retain transcripts or summaries of comment forums during the development of a major regional power policy and places the requirement that the notice of policy alternatives be published in the Federal Register or elsewhere in subsection I.

E. Public Meetings. This is a new part which describes alternative ways that BPA can interact with the public in addition to public comment forums. In response to a comment, the final policy clarifies that public meetings can be used to exchange technical information. Also, as with other notice requirement, the description of how BPA will notify the public of meetings has been moved to subsection I.

F. Time Allowed for Public
Recommendations or Comment and for
Notice of Hearings and Meetings. This
new part describes the length of time
which BPA will ordinarily allow for
written comments and for notice of
hearings and meetings. These are
minimum periods of time. Whenever
possible, BPA will provide earlier
notices. BPA will also consider special
requests for extensions of time in which
to submit comments.

G. Decision Document. This document contains essentially the same information as the previously required evaluation of the official record and the record of decision which it replaces.

Though not required by the policy, BPA may circulate all or parts of the decision document in draft form for public comment. BPA has found that this practice can help to ensure that BPA has fully understood and adequately evaluated comments which have been submitted. In the final policy, this part includes a description of the contents of the decision document.

H. Notice of Final Policy. This action concludes the development of a major

regional power policy.

I. Methods of Public Notification and Contact. In the final policy, this new part contains all requirements for providing notice and includes information on how BPA will use publications, direct mail, and personal contact to give this notice.

J. Combination of Other Required Notices with Policy Notices. This part has been added to the final policy to explain that, when it is desirable to do so, the Administrator may combine other required notices with notices specified for major regional power

K. Procedures for Expedited Decisionmaking, Under the Procedure for Public Participation in Major Regional Power Policy Formulation, PBA could only waive the requirements for major regional power policies when an emergency situation existed. The final Policy for Public Involvement permits the use of expedited procedures under more circumstances. These circumstances are still expected to be rare. For example, a sudden and shortlived opportunity to make a regionally beneficial decision, where that decision establishes a major regional power policy, would be the type of situation in which fulfilling all procedural requirements for major regional power policies would be impracticable. That is, a delay in the decision would make it impossible to capture the economic benefit of the decision. Similarly, an emergency situation, such as a sudden finding that a resource or utility practice could endanger the public, could also make any delay in a decision contrary to the public interest.

Several changes were made to the proposed language of this part. One simplifies the wording which describes how a decision is made to use an expedited procedure. Another substitutes the word, "impracticable," as used in the Administrative Procedure Act, for the proposed "impractical." No change in meaning is intended. Finally, the proposed procedure has been revised to require the Administrator to fulfill all practicable public involvement procedures and use alternative means of

informing and involving the public before a final policy is issued as well as before an interim policy is adopted.

L. Public Record. This part has been added to describe the purpose and contents of the record for development of a major regional power policy.

Section VI. Public Involvement for Other Actions. This section is included in the policy to reflect the full range of public involvement activities which BPA currently undertakes and which it intends to continue. BPA's practice has been to inform and involve the public on many issues which are not defined as major regional power policies. The section describes the types of actions for which the Administrator may conduct public involvement and the factors for determining the appropriate level and type of public involvement activities which may be most appropriate and effective.

A. Other BPA Actions for Which the Administrator May Conduct Public Involvement. The Administrator may also determine that it is appropriate to conduct public involvement on actions other than major regional power policies. Such other actions may include:

1. Formulation of policies which are not major regional power policies.
Certain policies may affect future BPA actions but may not be identified as major regional power policies. The development of BPA's Conservation Cost-Sharing Principles is an example of how BPA can involve the public in discussion of a policy which is not a major regional policy.

2. Planning activities and the development of plans related to areas such as energy conservation, renewable and other generating resources, fish and wildlife resources, and the transmission system. BPA develops regular plans to guide its decisions. These plans include projections for the power demands which BPA anticipates, the resources which must be acquired to meet these demands, changes or additions which are required to the transmission system, and other activities which occur on a cyclical basis. Information provided by the public may assist BPA in the preparation of these plans.

3. Development and implementation of programs related to areas such as energy conservation, renewable and other generating resources, fish and wildlife resources, and the transmission system. Once basic policies and action plans are in place, BPA develops and carries our specific programs. These programs include research and development activities, the acquisition

of energy conservation and other energy resources, and construction and maintenance of transmission facilities. These programs affect specific publics and may be improved by information provided by the public.

4. Other BPA actions related to major regional power issues. These actions typically involve on-time decisions which have a major impact upon BPA or the region. They are not, however, expressed in a formal policy document which is adopted to guide future actions. Decisions to pursue new marketing opportunities, to explore the feasibility of special programs, and to reach agreements having significant economic impacts are examples of these types of actions.

B. Factors for Determining the Appropriate Level of Public Involvement. Once a decision has been made that the public should be involved in a particular issue or action, the specific ways in which the public will be informed and encouraged to participate must be determined. To be most effective, these methods should relate closely to the type of activity concerned and the process which will be followed to reach a final decision. The wide range of actions which are covered in the category of Other BPA Actions precludes definition of a single public involvement process which will suit all situations. For this reason, certain factors which may bear on the selection of appropriate public involvement techniques have been identified.

Issued in Portland, Oregon, on July 18, 1986.

Peter T. Johnson,

Administrator.

[FR Doc. 86-17064 Filed 7-29-86; 8:45 am]

Office of Energy Research

Energy Research Advisory Board; Physics Review Panel, Meeting

Notice is hereby given of the following meeting:

Name: Physics Review Panel of the Energy Research Advisory Board (ERAB).

Date and Time: August 25, 1986—8:30 a.m.-4:00 p.m.

Place: Sheraton Inn. Directors Room, 90– 100 Grand Central Parkway, East Elmhurst, NY 11369, (718) 446–4800

Contact: William L. Woodard, Department of Energy, Office of Energy Research, 1000 Independence Avenue SW., Washington, DC 20585, (202) 252-5767

Purpose of the Parent Board

To advise the Department of Energy

(DOE) on the overall research and development conducted in DOE and to provide long-range guidance in these areas to the Department.

Purpose of the Panel

The Physics Review Panel is a subgroup of ERAB and reports to the parent Board. The Physics Review Panel will review the National Research Council's report, "Physics through the 1990's and, in particular, assess its specific suggestions for initiatives that are recommended for the Department of Energy.

Tentative Agenda

August 25, 1986

- Summary reports on the following areas:
 - —Atomic, molecular, and optical physics
- -Condensed-matter physics
- -Elementary particle physics
- -Gravitation, cosmology, and cosmic-ray physics
- -Nuclear physics Plasmas and fluids
- Preliminary discussion of recommendations and priorities
- Public Comment (10 minute rule)

Public Participation

The meeting is open to the public. Written statements may be filed with the Panel either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact William Woodard at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provisions will be made to include the presentation on the agenda. The Chairperson of the Panel is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Minutes of the Meeting

Available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC between 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC on July 22, 1986. Charles E. Cathey,

Deputy Director, Science and Technology Affairs Staff, Office of Energy Research. [FR Doc. 86-17130 Filed 7-29-86; 8:45 am] BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. ER86-600-000, et al.]

Arizona Public Service Co. et al.; Electric Rate and Corporate Regulation Filings

Take notice that the following filings have been made with the Commission:

1. Arizona Public Service Co.

[Docket No. ER86-600-000] July 24, 1986.

Take notice that on July 17, 1986.
Arizona Public Service Company (APS)
tendered for filing an Economy Energy
Interchange Agreement between
Arizona Public Service Company (APS)
and Imperial Irrigation District (IID),
executed June 13, 1986.

APS requested that this Agreement become effective 60 days from the date of filing with FERC.

Copies of this filing are being served upon IID and the Arizona Corporation Commission.

Comment date: August 5, 1986, in accordance with Standard Paragraph E at the end of this notice.

2. Carolina Power & Light Co.

[Docket No. ER86-507-000] July 23, 1986.

Take notice that on July 21, 1986, Carolina Power & Light Company ("CP&L") tendered for filing in this docket an Amendment, dated July 8. 1986, which incorporates Amendments dated January 16, 1986, and May 1, 1986. between the City of Fayetteville ("Customer") and CP&L to the Service Agreement dated October 27, 1972, which is on file with the Commission as CP&L Rate Schedule FPC No. 102. The Amendments provided for the supplying of Backstand and Replacement Power by CP&L for Customer's generation and the purchase by CP&L from Customer of Peak, Reserve and Surplus Power when such is available from Customer.

Appendix E, dated July 8, 1986, amends the Amendment dated May 1, 1986 by deleting a paragraph on Replacement Page 18, dated April 28, 1986. This deletion from the Amendment, dated May 1, 1986, eliminates purchases of Standby Service from a third party. Appendix E also amends Appendix A, which consists of three pages, by allocating Administrative and General Expenses and General Plant between power production plant, transmission plant, and distribution plant based on the labor ratios of these items and by the addition of a transmission facilities

acquisition adjustment. It is proposed that the Amendment, dated July 8, 1986, become effective on the same date as the filing tendered May 27, 1986 in this docket.

Comment date: August 5, 1986, in accordance with Standard Paragraph E at the end of this notice.

3. Long Island Lighting Co.

[Docket No. ER86-475-000] July 23, 1986.

Take notice that on July 21, 1986, Long Island Lighting Company ("LILCO") tendered for filing a proposed supplement to its Contract No. 96 between LILCO and the Incorporated Village of Rockville Centre for the interchange of emergency electric power between them.

The purpose of this supplement to the interchange agreement is for Rockville Centre to provide LILCO with 8,000 kw of firm capacity for the time period November 1, 1985 to October 31, 1986; to set the price of any energy provided during that time period; and to enable Rockville Centre continued access to LILCO's transmission system during that time period.

Copies of this filing were served upon the New York Power Authority, The Municipal Electric Utilities Association of New York State, the Incorporated Village of Rockville Centre and the New York Public Service Commission.

Comment date: August 5, 1986, in accordance with Standard Paragraph E at the end of this notice.

4. Pacific Power & Light Co., an assumed business name of PacifiCorp

[Docket No. EP86-802-000] July 24, 1986.

Take notice that on July 17, 1986,
Pacific Power & Light Company (Pacific),
an assumed business name of
PacifiCorp, tendered for filing Exhibit A,
Revision No. 9, dated December 20, 1985
to the February 25, 1976 Transmission
Agreement (Pacific's Rate Schedule FPC
No. 123), between Pacific and Tri-State
Generation and Transmission
Association, Inc. (Tri-State).

Exhibit A to the Transmission
Agreement is revised annually in
accordance with Article 6(b) of the
Agreement, and specifies the projected
maximum integrated demand in
kilowatts which Tri-State desires to
have transmitted to the respective
Points of Delivery for the immediate four
future years.

Pursuant to § 35.11 of the Commission's Regulations, Pacific respectfully requests that a waiver of prior notice be granted and an effective date of September 30, 1985, be assigned. This date being consistent with the provisions of section 6(b) of the Transmission Agreement.

Copies of the filing were supplied to Tri-State and the Wyoming Public Service Commission.

Comment date: August 5, 1986, in accordance with Standard Paragraph E at the end of this notice.

Towns of Erath, Gueydan, and Kaplan, LA v. Gulf States Utilities Co.

[Docket No. EL86-48-000] July 22, 1988.

Take notice that on July 10, 1986, the towns of Erath, Gueydan, and Kaplan, Louisiana ("Towns") filed a complaint against Gulf States Utilities Company ("Gulf States") under Sections 206 and 306 of the Federal Power Act.

The Towns allege that as a result of a rate increase that Gulf States has requested in Docket No. ER86-558-000, they will be placed in a severe price squeeze. They further claim that because of extremely low retail rates in Louisiana it is possible that the Commission may choose not to remedy the price squeeze fully merely by lowering the rates. Accordingly, as an alternate form of relief from the price squeeze, the Towns request that the Commission modify the existing terms and conditions of their arrangements with Gulf States to permit them to obtain wholesale power from alternate suppliers immediately, rather than wait until the present contractual arrangements can be terminated on May

The Towns also request that the Commission modify the existing terms and conditions of Gulf States' service as described above on two alternate grounds: (1) That the present contractual arrangements were entered into as a result of a mutual error on the part of all parties, and (2) that during the negotiations of the existing contractual arrangements the Towns relied on material representations made by Gulf States which Gulf States knew or should have known were not true.

Comment date: August 21, 1986, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be

considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-17106 Filed 7-29-86; 8:45 am]

[Docket No. TA86-3-59-002]

Northern Natural Gas Co., Division of Enron Corp.; Change in Tariff Rates

July 25, 1986.

Take notice that on July 22, 1986, Northern Natural Gas Company, Division of Enron Corp. (Northern), tendered for filing with the Commission to be effective August 10, 1986 the following tariff sheet to be included in Northern's FERC Gas Tariffs.

Third Revised Volume No. 1 Substitute Forty-First Revised Sheet No. 4a

On July, 11, 1986 Northern filed with the Commission certain tariff sheets to reflect its purchased gas costs from Canadian suppliers on an "as-billed" basis. Northern proposes to move to its D-2 demand sales rate only the demand portion of its Canadian costs while leaving the commodity portion of its Canadian costs in its gas sales commodity rates. Upon review of the D-2 demand rate derivation, it was determined that Northern inappropriately assigned 100% of the demand costs to its Market Area sales rates instead of 94% of such demand costs. Consequently, the D-2 demand rate will increase by 4.64¢ per Mcf rather than 4.94¢ per Mcf, as previously submitted, as detailed on Revised Schedule B-1 attached hereto. All other details of the original filing remain the

Copies of the filing were served on all of Northern's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825
North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, 385.211). All such motions or protests should be filed on or before August 1, 1986. Protests will be considered by the Commission in determining the

appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-17109 Filed 7-29-86; 8:45 am]

[Docket No. RP86-128-001]

Ohio River Pipeline Corp.; Proposed Changes in FERC Gas Tariff

July 25, 1986.

Take notice that Ohio River Pipeline Corporation (Ohio River) on July 7, 1986, tendered for filing Substitute Original Sheet Nos. 11, 12, 17 and 18 of its FERC Gas Tariff, Original Volume No. 1. According to § 381.103(b)(2)(iii) of the Commission's regulations (18 CFR 381.103(b)(2)(iii)), the date of filing is the date on which the Commission receives the appropriate filing fee, which in the instant case was not until July 22, 1986.

Ohio River states that the revised tariff sheets are being filed pursuant to Ordering Paragraph (B) of the Commission's Order issued June 30, 1986 requiring that revised tariff sheets reflecting rates developed by using projected units of transportation be filed within five days of the issuance of the Order.

Ohio River requests waiver of all Commission rules and regulations, as necessary, to permit the tendered tariff sheets to become effective on July 1, 1986.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825
North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, 385.211 (1985)) All such motions or protests should be filed on or before August 1, 1986. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make

protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-17110 Filed 7-29-86; 8:45 am] BILLING CODE 6717-01-M

[Docket No. RP86-8-002]

Transwestern Pipeline Co.; The Filing of an Order 94 Report

July 25, 1986.

Take notice that on July 18, 1986, pursuant to the Commission's December 12, 1985, order. Transwestern Pipeline Company (Transwestern) tendered for filing Schedules outlining the additional Order 94 costs (\$990,872.52) verified subsequent to its May 1, 1986 filing, and Schedules supporting the Order 94 costs estimated to be paid prior to the sixmonth billing period.

In addition, Transwestern has submitted a Summary Schedule which summarizes the allocated Order 94 costs by customer submitted in the May 1. 1986 filing, the additional Order 94 costs verified and paid since the May 1, 1986 filing and the Order 94 costs that are to be verified and paid prior to the termination of the second six-month period. Also, Transwestern has submitted information required under § 271.1104(f) of the Commission's regulations and the relevant contractual provisions supporting the Order 94 costs paid by Transwestern, to the extent such information has not been previously filed with the Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, 385.211 (1985)). All such motions or protests should be filed on or before August 1, 1986. Protests will be considered by the Commission in determining the appropriate action to be

taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-17111 Filed 7-29-86; 8:45 am]

[Docket No. Cl86-516-000 et al.]

PSEC, Inc.; Applications for Abandonment

July 22, 1986.

Take notice that each of the applicants listed herein has filed an application pursuant to section 7 of the Natural Gas Act for authorization to abandon service, as described herein.

The circumstances presented in the applications meet the criteria for consideration on an expedited basis, purusant to § 2.77 of the Commission's rules as promulgated by Order Nos. 436 and 436-A, issued October 9, and December 12, 1985, respectively, in Docket No. RM85-1-000, all as more fully described in the applications which are on file with the Commission and open to public inspection.

Any person desiring to be heard or to make any protest with reference to said applications should on or before 15 days after the date of publication of this notice in the Federal Register, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceedings. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Kenneth F. Plumb, Secretary.

Docket No. and date filed	Applicant	Purchaser and Location	Price per Manufac- turer	Presura base
CI86-516-000, B, * June 16, 1986	PSEC, Inc., Suite 200, 100 Park Avenue Building, Oktahoma City, OK 73102	Arkla Energy Resources, a division of Arkla, Inc., Kinta Field, Haskell County, OK	(2)	
Cl86-518-000, B, ¹ June 16, 1986	do. J.O. Clark, Jr., d/b/a Clark Fuel Producing Company, 727 Houston Club Building, Houston, TX.77092.	do. Valero Interstate Transmission Company, various contracts and locations.	(2)	

Docket No. and date filed	Applicant	Purchaser and Location	Price per Manufac- turer	Presure base
Cl86-583-000, B, June 16, 1986	Vernon E. Faulconer, 1001 E.S.E. Loop 323, Suite 160, P.O.Box 7995, Tyler, TX 75711.	Texas Gas Transmission Corporation, D.M. Rob- inson No. 1 well, Maxie Field, Acadia Parish, LA.		

Additional information received July 9 and 15, 1986,
Applicant, a small producer certificate holder in Docket No. CS72-36-001, requests authorization in Docket Nos. Cl86-518-000, Cl86-517-000 and Cl86-518-000 for a partial abandonment for an indefinite term of a sale of gas to Arkla from the respective Farmer #1-31, Shaw A#1-3 and Hightower #1-19 wells which produce NGPA section 104-1973-1974 beliennium gas. Applicant indicates that its share of deliverability in the wells is approximately 1.12 MMcf per day. Applicant states that Arkla retains the right to recall the gas at anytime upon 30 days notice. Applicant states that Arkla is not paying for gas not taken and Applicant desires to find other markets for the gas.

Additional information received July 10, 1986.
Applicant, which operates under a small producer certificate in Docket No. CS71-438, requests blanket limited-term abandonment authorization for gas released by VITCO. Applicant also requests pre-grained abandonment authorization for any sales of such released gas made under its small producer certificate. Applicant states it is willing to accept a limited-term abandonment without prejudice to its rights to apply for further abandonment in the future or for any other reason. Applicant states that it has been subjected to substantially reduced takes without payment. Applicant states that all of the subject gris qualifies under NGPA section 108, and as such the wells may be damaged by being shurin absent Commission authorization. Applicant further states that the current deliverability estimates are 200 Mcf/d. Applicant states it will grant VITCO certain reductions in its take-or-pay liabilities to the extent its gas is released.

authorization. Applicant further states that the current deliverability estimates are 200 monus. Applicant states it will grain virtoe established to the product of the Docket No. CS74–147, requests authorization to abandon a sale of gas to Texas Gas from the D.M. Robinson No. 1 well. Applicant states that the well is capable of delivering approximately 40 Mcf per day and that the contract calls for a price of approximately 49e per MMBtu. Applicant states that it is subject to substantially reduced takes without payment and that it desires to conduct production enhancement work on the well. Applicant states that Texas Gas is unwilling to renegotiate a price which would justify production enhancement work on the well. Applicant desires to sell the gas to another purchaser.

Filing Code: A—initial service; B—abandonment; C—Amendment to added acreage; D—Amendment to delete acreage; E—Total Succession.

[FR Doc. 86-17108 Filed 7-29-86; 8:45 am] BILLING CODE 6717-01

[Docket Nos. CP86-618-000 et al.]

Ringwood Gathering Co. et al.; Natural Gas Certificate Filings

Take notice that the following sfilings have been made with the Commission:

1. Ringwood Gathering Co.

[Docket No. CP86-618-000] July 24, 1986.

Take notice that on July 14, 1986, Ringwood Gathering Company (Ringwood), 100 West Fifth Street, Tulsa, Oklahoma 74103, filed in Docket No. CP86-618-000 an application pursuant to section 7 of the Natural Gas Act (Act) for blanket certificates under 18 CFR Part 157 Subpart F and Part 284 Subpart G, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The application states that Ringwood is engaged in the purchase, transportation and sale of natural gas, and is a natural gas company, as defined in the Act. Ringwood further states that it purchases natural gas jointly from certain producers in the Ringwood Field in Oklahoma, gathers gas in the field for delivery to a processing plant, and receives the residue gas at the tailgate of the processing plant for delivery through a 26-mile pipeline that interconnects with Northwest Central Pipeline Corporation, Ringwood's primary single customer, and Oklahoma Natural Gas Company, a division of ONEOK, Inc.

The application states further that on July 2, 1986, the Commission approved Ringwood's settlement proposal in Docket Nos. RP85-210 and CP86-116 in an order that, inter alia, required Ringwood to file an application for

blanket certificate authority in conformance with 18 CFR 284.221 and 157.203, and to file tariff sheets containing the rates, terms and conditions under which Ringwood will provide transportation services pursuant to 18 CFR Part 284, within 10 days after the order's issuance. Ringwood states that this application is made in compliance with the Commission's order.

In its application, Ringwood certifies that in providing transportation services pursuant to the requested blanket authority in 18 CFR Part 284 Subpart G, it will fully comply with the requirements set forth in Subpart A of Part 284. Ringwood states that its volumetric transportation rates for this service will be set at a maximum of 39 cents per Mcf and a minimum of 10 cents per Mcf. These rates for firm and interruptible self-implementing transportation are set forth in Ringwood's tariff in Original Sheets 4-A and 4-B, which were appended to the settlement approved on July 2, 1986. With respect to its application for blanket authority under 18 CFR Part 157 Subpart F, Ringwood states that it will comply with the terms, conditions and procedures specified in that Subpart.

Comment date: August 8, 1986, in accordance with Standard Paragraph F at the end of this notice.

2. Iewa-Illinois Gas and Electric Co.

[Docket No. CP86-605-000] July 25, 1986.

Take notice that on July 8, 1986, Iowa-Illinois Gas and Electric Company (Applicant), P.O. Box 4350, Davenport, Iowa 52808, filed in Docket No. CP88-605-000 an application pursuant to section 1(c) of the Natural Gas Act for a Hinshaw exemption from the provisions of the Natural Gas Act and the Regulations of the Commission thereunder (1) declaring its gas facilities and operations in certain areas in the

State of Iowa exempt from the provisions of the Natural Gas Act, and (2) vacating the Commission certificates of public convenience and necessity associated with said areas, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that its gas facilities and operations in Iowa, sometimes referred to as its operating districts in Fort Dodge (Area 1), Ottumwa (Area 2), Cedar Rapids / Iowa City (Area 3), and Applicant's Muscatine/West Liberty-Wilton System (including Wilton-Durant and Wilton Extensions) (Area 4) are eligible for an exemption from the provisions of the Natural Gas Act. Applicant states that its rates, services and facilities in the State of Illinois are regulated by the Illinois Commerce Commission and that rates, services and facilities in Iowa are regulated by the Utilities Board of the Iowa Department of Commerce (IUB). Areas 1, 2, 3 and 4 are located entirely within Iowa and are spearate distribution systems not interconnected with each other by the facilities of Applicant, it is stated. Area 1 is served from the pipeline system of Northern Natural Gas Company (Northern) and Areas 2, 3 and 4 are served from the pipeline system of Natural Gas Pipeline Company of America (Natural), it is stated. Applicant states further that all gas received in Areas 1, 2, 3, and 4 is consumed within Iowa. Applicant indicates that it has facilities in each of these areas which have been certificated by this Commission and that facilities are used only to transport natural gas from the delivery point of Northern or Natural, as applicable, to Applicant's distribution facilities in these non-integrated areas.

In order to avoid duplicate regulation of its distribution facilities by this Commission and the IUB, and in order to clarify Applicant's status as a local

distribution company for purposes of the Natural Gas Act, section 311 of the Natural Gas Policy Act, and Order No. 436, the Applicant seeks a Hinshaw exemption for its Iowa Areas 1 through 4 and further requests that the Commission vacate the following certificates:

Area 1: G-303 (in part)

Area 2: G-303 (in part), G-1899 (in part), G-2012

Area 3: G-303 (in part), G-1721, G-18138, CP64-123, CP70-192, CP76-334, CP79-308

Area 4: G-20593, G-62-4, G-82-393-000.

Comment date: August 15, 1986, in accordance with Standard Paragraph F at the end of this notice.

3. Tricentrol Interstate Pipeline Inc.

[Docket No. CP86-616-000] July 24, 1986,

Take notice that on July 14, 1986, Tricentrol Insterstate Pipeline Inc. (Tricentrol), Five Post Oak Park, Suite 1910, Houston, Texas 77027, filed in Docket No. CP86-616-000, an application pursuant to section 7(c) of the Natural Gas Act for authorization to acquire, own and operate natural gas transmission facilities located in the state of Montana, authorization to perform transportation services and blanket certificate authorization to provide (Order No. 436) open access, nondiscriminatory transportation, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Tricentrol states that in intends to purchase the transportation facilities of Northern Natural Gas Company, a Division of Enron Corporation (Northern) located in Hill, Blaine and Chouteau Counties, Montana. Northern is said to seek abandonment authority in an application filed July 9, 1986 in Docket No. CP86-607-000. It is said that Northern's Montana facilities were constructed and operated pursuant to Commission authority for the purpose of producing natural gas in the Bearpaw field, containing the Tiger Ridge and Sherard fields, for Northern's system supply. It is also stated that because of Northern's current market situation much of the Bearpaw field production is shut in or producing at substantially reduced levels. Further, Tricentrol states that as part of the acquisition agreement Northern has agreed to release certain non-regulated natural gas production of Tricentrol United States, Inc. (TUSI) from existing contracts; such release may relieve Northern of certain take-orpay exposure and allow TUSI to market its gas in the sport market.

Tricentrol states that after authorizations are granted and the proposed sale completed it would own and operate the main high pressure transmission pipeline from and including the Blaine County No. 1 compresser station to the Canadian border. Tricentrol requests authority for the acquisition and to own and operate these facilities. Tricentrol also requests authority to continue the interstate transmission services Northern seeks to abandon.

In addition to these authorizations
Tricentrol requests blanket certificate
authority to become an open-access
nondiscriminatory transporter pursuant
to part 284 of the Commission's
Regulations. In its pro forma tariff,
Tricentrol states that its initial
transportation rate would be 21.1¢ per
Mcf of natural gas transported.
Tricentrol further states that it is still in
the process of negotiating service
agreements with prospective shippers.

Tricentrol estimates the acquisition cost of these interstate facilities, based on net book value as of December 31, 1985, to be \$5,314,567. Tricentrol also states that another affiliate, Tricentrol Gathering Company, Inc., would acquire, own and operate the non-jurisdictional gathering facilities to be abandoned by Northern.

Comment date: August 8, 1986, in accordance with Standard Paragraph F at the end of this notice.

4. Tricentrol Interstate Pipeline

[Docket No. CP86-617-000]

July 24, 1986.

Take notice that on July 14, 1986, Tricentrol Insterstate Pipeline Inc. (Tricentrol), Five Post Oak Park, Suite 1910, Houston, Texas 77027, filed in Docket No. CP86–617–000 an application purusant to Executive Order 10485, as amended by Executive Order 12038, and Delegation Order No. 0204–111, for a Presidential Permit to own, operate and maintain border facilities on the United States-Canadian border, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Tricentrol states that it has applied on July 14, 1986 in Docket No. CP86-616-000 for authority to acquire from Northern Natural Gas Company, Division of Enron Corporation (Northern), Northern's interstate pipeline facilities located in Blaine County, Montana. It is stated that Northern was granted Presidential Permit authority by Commission order of May 11, 1982. By its application. Tricentrol states that it

proposes to succeed Northern's interest by purchase and requests a Presidential Permit authorizing Tricentrol to own, operate and maintain the border facilities located near Willow Creek, Saskatchewan. Tricentrol states that Northern filed on July 9, 1986 an application in Docket No. CP86–607–000 for authorization to abandon said facilities. Tricentrol requests Presidential Permit authority to transport and export up to the design capacity of these facilities, stated at 150,000 million cubic feet of natural gas per day, for the account of others.

Comment date: August 8, 1986, in accordance with Standard Paragraph F at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be

unnecesary for the applicant to appear or be represented at the hearing. Kenneth F. Plumb,

Secretary.

[FR Doc. 86-17107 Filed 7-29-86; 8:45 am] BILLING CODE 6717-01-M

Texas Eastern Transmission Corp; **Applications**

Nos. RP85-177-000, RP85-177-016, RP85-177-017, RP85-176-000, RP85-176-007, RP85-176-008, RP83-35-000, RP81-109-000, RP74-41-000, TA85-5-17-000, and TC86-3-000. Order granting appeals and permitting interventions out of time, establishing procedures for the submission of other petitions to intervene out of time, and establishing procedures for the

Acting Chairman; Charles G. Stalon, Charles A. Trabandt and C. M. Naeve.

Issued July 23, 1986.

In this order we address three matters concerning the settlement filed by Texas **Eastern Transmission Corporation** (Texas Eastern) on March 13, 1986, to resolve the issues raised in Docket No. RP85-177 and to implement Order No. 436 et seq.1

Appeals From Denials of Petitions for Late Intervention

The first matter concerns the appeals of Marathon Oil Company (Marathon) and Arco Oil and Gas Company (Arco) from the law judge's denial of their petitions to intervene out of time.2 Both petitions were filed well beyond the August 16, 1985 deadline for filing petitions to intervene specified in the notice published in the Federal Register to inform the public of the scope of the proceeding: Marathon filed its petition on April 24, 1986, while Arco filed its petition on May 13, 1986. But this fact is not important. Marathon and Arco wish to intervene in this case because the settlement determines the rates, terms, and conditions under which Texas Eastern will operate as an open access transporter pursuant to Order No. 436. The original filing in this case, however, did not purport to determine these rates, terms, and conditions; the notice Texas Easter submitted with its filing for publication in the Federal Register, and which was published, did not suggest that these rates, terms and conditions would be determined in this case; and

Texas Eastern has never submitted for publication in the Federal Register an amended notice to inform the public that the scope of the proceeding had been expanded to include the determination of these rates, terms, and conditions. In these circumstances the only relevant question is, as we have previously noted in this case, whether Marathon and Arco petitioned to intervene "within a reasonable time after receiving adequate notice of the expanded nature

The judge concluded that neither had. We disagree. Given Texas Eastern's failure to have a notice published in the Federal Register informing the public that the rates, terms, and conditions under which Texas Eastern will operate as an open access transporter will be determined in this case we cannot say that either Marathon or Arco unreasonably delayed filing their petitions. Accordingly, we shall grant the petitions of Marathon and Arco to intervene and allow both companies to participate in the case with the full rights of parties including, but not limited to, the right to file comments on the settlement.

Our decision to allow Marathon and Arco to intervene and file comments on the settlement is not based solely on our finding that neither unreasonably delayed filing their petitions to intervene. This case presents many issues of first impression that are of considerable significance to our implementation of Order No. 436. "In such a case it is important to have a broad range of views."4 This is especially important in this case. Essentially what has happened here is that Texas Eastern initiated a traditional rate case in which the traditional parties intervened. These parties then expanded the scope of the proceeding to resolve by settlement wholly untraditional issues concerning the implemention of Order No. 436. These issues affect many persons-such as producers like Marathon and Arco-that do not intervene in traditional rate cases and did not intervene in Texas Eastern's. Since these persons did not have an opportunity to participate in the negotiation of the settlement, their comments on the settlement must be heard.5

Procedures Dealing With Other Petitions To Intervene Out of Time

The second matter concerns other petitions to intervene out of time. We are aware that persons besides Marathon and Arco have sought to intervene out of time. But these petitions are not now before us. It is also possible that other persons will seek to intervene when they learn of the issues presented by the settlement. As we have done with other petitions in this case, we could address each of these petitions as they come before us. Doing so, however, could significantly delay a final decision on the merits. We wish to avoid that. Accordingly, we shall adopt the following procedures for dealing with other possible petitions to intervene out of time. First, we shall direct the Secretary to have this order published promptly in the Federal Register. This will give the public notice that the rates, terms, and conditions under which Texas Eastern will operate as an open access transporter pursuant to Order No. 436 will be determined in this case. Second, we shall require any person seeking to intervene to do so within 15 days of the date this order is published in the Federal Register. 5 Third, we shall require all persons seeking to intervene to file, if they wish, comments on the settlement by the same date. Any reply comments must be filed no later than 10 days thereafter.

Procedures for Filing Evidence To Support the Settlement

The third matter concerns the merits of the settlement itself. As we have noted, the settlement establishes the rates Texas Eastern will charge for transportation offered pursuant to Order No. 436. These rates must, among other things, be designed "to recover costs on the basis of projected units of service"7 and the costs to be recovered must be "properly allocated to the service to which the rate applies."8 Several commenters point out that it is impossible to tell from the material submitted with the settlement whether the settlement's rates comply with the requirements of Order No. 436.9 This is correct. Appendix A to the settlement sets forth the settlement cost of service on a total company basis. Article I of the settlement provides that the rates are

Texas Eastern Transmission Corp. Docket of the proceedings."3 submission of data. Before Commissioners: Anthony G. Sousa,

¹ Regulation of Natural Gas Pipelines After Partial Wellhead Decontrol, 50 FR 42408 (Oct. 18, 1985) (Order No. 436), modified, 50 FR 52217 (Dec. 23, 1985) (Order No. 436-A), pet. for review filed sub nom., Associated Gas Distributors v. FERC, No. 85-1811 (D.C. Cir., filed Dec. 12, 1985).

² By Order issued on June 5, 1986, the law judge permitted the appeals.

³ Texas Eastern Transmission Corp., 35 FERC 9 61.172 (1986).

^{*} El Paso Natural Gas Co., 35 FERC ¶ 61.440, slip op. at 42 (1986).

⁵ United Gas Pipe Line Co., 35 FERC ¶ 61,179 at 61,421 [1988] ("[T]he Commission would view with disfavor any proposed settlement dealing with Order No. 436 issues which did not allow all interested persons an adequate opportunity to have their positions considered."].

[&]quot;We will address any opposition to a petition to intervene in our order on the settlement.

⁷ See 18 CFR 284.7(d)(2) (1985).

^{*} See 18 CFR 284.7(d)(4) (1985).

⁹ See Initial Comments for Allied Corporation, at 3-4; Initial Comments for Consolidated Edison Company, at 8; Initial Comments for Producer-Marketer Transportation Group, at 9.

based on a total company throughput (both sales and transportation) of 1,100 million dth, and Article VI provides that the rates are based on the use of the modified fixed-variable method of cost classification and rate design. But these facts, which are not contested, do not enable either the parties or us to determine whether the individual transportation rates are designed to recover properly allocated costs on the basis of the units projected to be transported. Consequently, at this time we cannot find that there is substantial evidence in the record to support the settlement. Nor can we find that there is no genuine issue of material fact.10

In other cases where the company has failed to provide adequate support for the settlement's rates we have remanded the case to the presiding judge and required the company either to present evidence to support the settlement's rates or present evidence to support its filing.11 We will not do so here, however. A hearing could be quite time consuming. Yet the case needs to be resolved as quickly as possible consistent with our obligations under the Natural Gas Act. Moreover, the lack of data to support and explain the derivation of the transporation rates may be due to an oversight on Texas Eastern's part. The data may exist. And if it is made public, the concerns raised by the commenters may be satisfied. Accordingly, we shall require Texas Eastern to file workpapers, schedules, and a narrative explanation in sufficient detail to show how the transportation rates are derived from the settlement's cost of service. 12 Texas Eastern shall make this filing 10 days from the date of this order and serve copies of the filing on all parties and on all persons that have petitioned to intervene. All parties and persons that have petitioned to intervene shall, if they wish, file comments on the data Texas Eastern has been directed to provide within 15 days of the date this order is published in the Federal Register. Any reply comments must be filed no later than 10 days thereafter.

We must make one or the other finding before we may consider the settlement. See Rule 802(h)[1]. 18 CFR 385.602(h)[1]. The Commission orders

(A) The petitions of Marathon and Arco to intervene are granted.

(B) Any other person seeking to intervene shall file a petition to intervene within 15 days of the date this order is published in the Federal Register.

(C) Within 10 days of the date of this order, Texas Eastern shall file workpapers, schedules and a narrative explanation in sufficient detail to show the derivation of the settlement's rates.

(D) Marathon and Arco, as well as any person that has sought to intervene in this proceeding and has not filed comments on the settlement, may file initial comments on the settlement and the material filed by Texas Eastern pursuant to Ordering Paragraph (C) within 15 days of the date this order is published in the Federal Register. Any person wishing to do so must file its reply to these comments no later than 10 days thereafter.

(E) Any person that has previously filed comments on the settlement may file supplemental comments on the material filed by Texas Eastern pursuant to Ordering Paragraph (C) 15 days from the date this order is published in the Federal Register. Any person wishing to do so must file its reply to such comments no later than 10 days thereafter.

(F) The Secretary shall cause this order to be promptly published in the Federal Register.

By the Commission. Kenneth F. Plumb,

Secretary.

[FR Doc. 86-17238 Filed 7-29-86; 8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[OPP-180696; FRL-3054-7]

Application for Emergency Exemption To Use B-(4-Chlorophenoxy)-A-(1, 1-Dimethylethyl)-1H-1,2,4-Triazole-1-Ethanol; Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA). ACTION: Notice.

SUMMARY: EPA has received a request for an emergency exemption from the Kentucky Department of Agriculture (hereafter referred to as the "Applicant") to use the active ingredient B-(4-chlorophenoxy)-a-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol (Baytan TM 30 FL) to control

loose smut disease (*Ustilago nuda*) on 9,200 bushels of barley seed in Kentucky. Baytan ™ 30 FL contains an as yet unregistered active ingredient and, therefore, in accordance with 40 CFR 166.24, EPA is soliciting comment before making the decision whether or not to grant the exemption.

DATE: Comments must be received on or before August 14, 1986.

ADDRESS: Three copies of written comments, bearing the identifying notation "OPP-180696," should be submitted by mail to:

Information Services Section, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, bring comments to: Rm. 236, CM#2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information (CBI)." Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for inspection in Rm. 236 at the address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holiday.

FOR FURTHER INFORMATION CONTACT:

By mail: Libby Pemberton, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency 401 M St., SW., Washington, D.C. 20460.

Office location and telephone number: Rm. 716A, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, VA, (703–557–1806).

SUPPLEMENTARY INFORMATION: Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (17 U.S.C. 136p), the Administrator, may, at this discretion, exempt a State agency from any provision of FIFRA if he determines that emergency conditions exist which require such exemption.

The Applicant has requested the Administrator to issue a specific exemption to permit the use of the unregistered fungicide, B-(4-chlorophenoxy)-a-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol (CAS 55219-

¹¹ Southern Pacific Pipe Lines, Inc., 35 FERC ¶61,226 (1986); Central Illinois Public Service Co., 21 FERC ¶61,297 (1982); see also Northwest Pipeline Co., 30 FERC ¶61,236 (1985).

¹² Since the reasonableness of the transportation rates turns on whether costs have been properly allocated, Texas Eastern will of course have to provide data to show its sales rates have been derived.

65–3] available as Bayton 30 FL from Gustafson Chemical Company, to control loose smut disease caused by the fungus *Ustilago nuda* in barley seed to be utilized as planting stock for seed fields in Kentucky. Information in accordance with 40 CFR Part 166 was submitted as part of this request.

The Applicant indicates that loose smut has become more serious apparently due to the inability of existing seed treatments to control the disease organism. According to the Applicant, Vitavax 200 has been the product of choice for the past several years, but recently its effectiveness against the disease has markedly declined. According to the Applicant, without effective control, large quantities of barley seed would have to be diverted from the seed production program and sold as feed. Direct losses from this diversion of seed barley to feed could potentially cost \$30,000 in 1986. Indirect losses from reduced yields due to planting seed having high levels of loose smut could be as much as \$300,000. The Applicant indicates that if adequate control of loose smut is not available, the future of the Kentucky barley seed production program is in serious doubt.

Baytan 30 FL will be applied at a maximum rate of 0.75 ounce of active ingredient per 100 pounds of seed. A total of 210 pounds of product will be required to treat 9200 bushels of seed. This amount of seed will plant approximately 6.133 acres. Applications would be made at seed treatment facilities prior to bagging the seed through October 1, 1986.

This notice does not constitute a decision by EPA on the application itself. The regulation governing section 18 require publication of notice in the Federal Register of receipt of an application for a specific exemption proposing use of a new chemical (i.e., an active ingredient not contained in any currently registered pesticide). Such notice provides for the opportunity for public comment on the application. Accordingly, interested persons may submit written views on this subject to the Program Management and Support Division at the address above. The comments must be received on or before August 14, 1988, and should bear the identifying notation "OPP-180696." All written comments filed pursuant to this notice will be available for public inspection in Rm. 236, Crystal Mall No. 2 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday,

except legal holidays.

The Agency, accordingly, will review and consider all comments received during the comment period in

determining whether to issue the emergency exemption requested by the Kentucky Department of Agriculture.

Dated: July 15, 1986.

Anne E. Lindsay,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 88-16651 Filed 7-29-86; 8:45 am] BILLING CODE 6560-50-M

[OPP-64004; FRL-3056-4]

Intent to Cancel Certain Pesticide Registration; Mada Medical Products, Inc. et al.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Intent to Cancel.

SUMMARY: EPA is issuing a notice of intent to cancel certain pesticide registrations under section 6(b) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The registrations which the Agency intends to cancel are held by registrants whom the Agency, after a good faith effort, has been unable to contact. Persons adversely affected by this notice may request a hearing.

DATES: All registrations will be cancelled at the end of 30 days from the date of publication or receipt of this notice by registrants, unless a hearing has been requested by a person adversely affected by this notice, or the Agency is provided with a correct and current address of an affected registrant.

A request for a hearing by an affected registrant must be received by the Agency on or before August 29, 1986 or 30 days after receipt by mail by the affected registrant of this notice, whichever is the later date.

A request for a hearing submitted by any other adversely affected person must be received on or before August 29, 1986.

ADDRESS: Hearing requests must be submitted to: Hearing Clerk [A-110], U.S. Environmental Protection Agency, 401 M St., SW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT:
Stanley J. Austin, Registration Support
and Emergency Response Branch,
Registration Division (TS-767C),
Office of Pesticide Programs, U.S.
Environmental Protection Agency, 401
M St., SW, Washington, DC 20460.

Office location and telephone number: Rm. 716C, Crystal Mall Building #2, 1921 Jefferson Davis Highway, Arlington, VA, (703)-557-4360.

SUPPLEMENTARY INFORMATION: Over the years, EPA has been unable to contact certain pesticide registrants at the

addresses on file at the Agency or appearing on current pesticide product labels. EPA's inability to communicate with these registrants impairs the Agency's ability to discharge its statutory mandate to regulate pesticide products and their impact on environment. Furthermore, it creates an undersirable situation in that some registrants may unknowingly be in violation of the Act and escape burdens assumed by other registrants in compliance with the Act.

Section 6(b) of FIFRA allows the Administrator to issue a notice of intent to cancel a pesticide's registration if that ". . . pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act. . . "

Section 3(c)(1)(A) of FIFRA and 40 CFR 162.10(a)(1)(ii) make it a condition of registration that a registrant's address be filed with the Agency and appear on the label of the registrant's pesticide product. In addition, section 12(a)(1)(E) of FIFRA makes it unlawful to distribute, sell, offer for sale, hold for sale, ship, delivery or offer for delivery to any person a misbranded pesticide. Under FIFRA section 2(a)(2)(C)(i). failure to have the registrant's correct address on the label of its pesticide product constitutes misbranding. Therefore, failure of a registrant to submit a correct address and include such address as part of the label of its pesticide products is in violation of the Act's provisions and is grounds for concellation of that registrant's registrations.

EPA issued a policy statement, published in the Federal Register of March 5, 1986 (51 FR 7634), indicating that the Agency may decide to initiate cancellation proceedings for registrations held by registrants whom the Agency has, after good faith efforts, been unable to contact by mail. This notice implements that policy.

This notice will be sent to all affected registrants by certified mail to the most current addresses the Agency has in its files. For the purposes of this notice, the Agency will consider validated non-delivery as receipt and the date of validated non-delivery as the date of receipt in those instances where actual receipt is not accomplished.

The impact of these cancellations on the agricultural economy is difficult to determine. It is believed that some or all of the pesticide products subject to this cancellation action are no longer on the market. Some of the pesticide products have no agricultural uses. At worst, the impact on the agricultural economy is expected to be slight.

Pursuant to section 6(b), the Secretary of Agriculture has reviewed this notice and has no comments. The Science Advisory Panel has waived its right (under section 25(d)) to review this notice.

Registrations Subject to Cancellation

The following registrations are subject to cancellation under this notice.

Mada Medical Products, Inc., 98 Somerset St., Garfield, NJ 07026. World Wide Chemicals, Inc., 9203 W. Bluemound Rd., Milwaukee, WI 53226. Sanavene Products Co., Clark F. Ross, 123 E. Washington St., Kirwood, MO 63122. Epact Corp., 109-117 Dobbin St., Brooklyn, NY 11222. Chemage Co., P.O. Box 269, Bay St. Louis, MS 39520. IAMA, Inc., P.O. Box 111 (off Summer St.), Marshfield Hills, MA 02051. Tech Products, Inc., Huntington Station, Shelton, CT 06484. Insecticide Corporation of America, Inc., 515 Madison Ave., New York, NY 10022. Griffin Industries, P.O. Box 4945, Winston Salem, NC 28103. Hibner Product MFG Co., 2526 Detroit Ave., Cleveland, OH 44113.	
Somerset St., Garfield, NJ 07026. World Wide Chemicals, Inc., 9203 W. Bluemound Rd., Milwaukee, WI 53226. Sanavene Products Co., Clark F. Ross, 123 E. Washington St., Kirwood, MO 63122. Epact Corp., 109-117 Dobbin St., Brooklyn, NY 11222. Chemage Co., P.O. Box 269, Bay St. Louis, MS 39520. IAMA, Inc., P.O. Box 111 (off Summer St.), Marshfield Hills, MA 02051. Tech Products, Inc., Huntington Station, Shelton, CT 06484, Insecticide Corporation of America, Inc., 515 Madison Ave., New York, NY 10022. Griffin Industries, P.O. Box 4945, Winston Salem, NC 28103, Hibner Product MFG Co., 2526 Detroit Ave., Cleveland, OH 44113.	ration No.'s
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Station, Shelton, CT 06484. Insecticide Corporation of America, Inc., 515 Madison Ave., New York, NY 10022. Griffin Industries, P.O. Box 4945, Winston Salem, NC 28103. Hibner Product MFG Co., 2526 Detroit Ave., Cleveland, OH 44113.	
ica, Inc., 515 Madison Ave., New York, NY 10022. Griffin Industries, P.O. Box 4945, Winston Salem, NC 28103. Hibner Product MFG Co., 2526 Detroit Ave., Claveland, OH 44113.	10588-3. an
Hibner Product MFG Co., 2526 10701-1. Detroit Ave., Cleveland, OH 44113.	
Detroit Ave., Cleveland, OH 44113.	
Dutch Masters Paint & Chemical Co. Ltd., 29 Wythe Ave., Brook- lyn, NY 11211.	
	nd 9573-2.
Blue Magic Co. of Ohio, Inc., Box 9612-1. 1116, Piqua, OH 95813.	
Selby Chemicals, Inc., 817 Spring 9858-1. Ln., P.O. Box 1288, Portsmouth, OH 45662.	
Hills Supermarkets, Inc., 50 9662-1. Emjay Blvd., Brentwood, NY 11717.	
East 44th St., New York, NY 3, and 9 10017.	150-2, 9150 150-4,
Bulk Insecticide Co., 3410 Harper 11376-400 St., Berkley, CA 94703.	
SLA Chemical Corp., P.O. Box 2023, Scottsdale, AZ 85252, Gasser & Dunham, P.O. Box 452, 11261-618	
Merrill, OR 97633. 11261-6	
ment Corp., 54 Kinkel St., 06. Westbury, NY 11590.	
	11602-3, 1, 11602-5, 3, and 11602
Larwin Chemical Co., 201 N.E. 10872-902 2nd St., Ft. Lauderdale, FL 33301.	28.
Bitter Lake Chemical Co., P.O. 11482-1. Box 7528, Seattle, WA 98133.	
Nuys, CA 91401. 4, and 8 Scott Laboratories, Inc., 860 11183-558 South 19th St., Richmond, CA 11183-9	
94804. Carpet Color Systems, Inc., 26– 20 Jackson Ave., Long Island City, NY 11101.	nd 9648-2.
Chemurg: Manuf. Corp., Box 11592-1, 34223, Dallas, TX 75234. 15592-3	11592-2, 8, 11592-4, 6, and 15592
Kathon, Inc., 112 No. 4th St., St. 10608-1.	

Louis, MO 63102.

Litton Dental Products, Box 1024, Toledo, OH 43601.

Registrant	Registration No.'s
Institute for Bio-Pharmaceutical Research (a Division of Arcadia Products Corp.), P.O. Box	10322-1.
3691, Hollywood, FL 33023. Thomas Labs., Inc., 6536 Waldorf Pl., Cincinnati, OH 45229.	10427-1.
Metal Powdersinc, 155 N. Dean St., Englewood, NJ 07631.	11503-1.
Tri State Supply, Inc., Box 9505, Denver, CO 80209.	11614-1.
Arrowhead Industries, Inc., 3 Center St., Denville, NJ 08734.	10730-2,
Sun Manufacturing Co., P.O. Box 36, Tahlequah, OK 74464.	10490-1.
March Chemical Co., Inc., 1464 Sierra Vista Dr., Baton Rouge, LA 70815.	10880-1, 10880-3, and 10880-4.
Melrose Chemical Co., Inc., 763 46th Ave., Oakland, CA 94601.	10100-2.
Echo, Inc., P.O. Box 1, Revere- Bucks County, PA 18953.	10143-2, and 10143-3.
Pettibone Lab., Inc., 11 East 44th St., New York, NY 10017.	10589-3, and 10589-4.
A. Sanderson & Company Ltd., c/ o Helsman USA Inc., S. Service Rd., Long Island Expressway, Westbury, NY 11590.	11266-1, 11266-2, 11266-3, and 11266- 6.
Sueco Special Paint Co., 84 Te- cumseh, Medford, NJ 08055.	10469-2.
MacDonald D.M. Labs., Inc., P.O. Box 8543, White Bear Lake, MN 55110.	10644-1.
Morgan Chemicals, Inc., P.O. Box 3002, Great Falls, MT 59401.	11544-16.
Western Products, Inc., Box 745, Orange, CT 06447.	11627-1, 11627-2, 11627-3, 11627-4, and 11627-5.
Sentinel Chemical Co., P.O. Box 853, Cakland, CA 94604.	11185-5239, and 11185-5240.
Acteen Pest Control Services, 1011 Heiz Ave., Berkeley, CA 94710.	10919-5618.
Domco Chemical Corp., 123rd Street & St. Nichlas Ave., New York, NY 10027.	10151-1.
H.P. Bohack Co., Inc., 4825 Met- ropolitan Ave., Brooklyn, NY 11237.	10580-1,
Jade Co., Inc., P.O. Box 1830, Indio, CA 92201.	10091-2,
Wilkins & James, Inc., 3345 Royal Ave., Oceanside, NY 11572.	10104-1.

Dated: July 21, 1986.

James W. Akerman,

Acting Director, Registration Division. [FR Doc. 86–16979 Filed 7–29–86; 8:45 am] BILLING CODE 6560–50–M

FEDERAL RESERVE SYSTEM

The Northern Virginia Banking Corp., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1844) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than August

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. The Northern Virginia Banking Corporation, Sterling, Virginia; to become a bank holding company by acquiring 100 percent of the voting shares of The National Bank of Northern Virginia, Sterling, Virginia, a de novo bank.

B. Federal Reserve Bank of San Francisco (Harry W. Green, Vice President) 101 Market Street, San Francisco, California 94105:

1. Oregon Pacific Financial, Inc., Portland, Oregon; to become bank holding company by acquiring 51.49 percent of the voting shares of Santiam Valley Bank, Aumsville, Oregon.

Board of Governors of the Federal Reserve System, July 24, 1986. William W. Wiles, Secretary of the Board. [FR Doc. 86-17028 Filed 7-29-86; 8:45 am] BILLING CODE 6216-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Assessment of Research in the Areas of Dietary and Blood Cholesterol and Dietary Calcium; Delegation of Authority

Notice is hereby given that on June 30, 1986, the Secretary of Health and Human Services delegated to the Assistant Secretary for Health (ASH), with authority to redelegate, the authority vested in the Secretary under section 1453 of the Food Security Act of 1985 Pub. L. 99–198. This delegation allows the ASH to conduct the assessment of existing scientific literature and research on: "the relationship between dietary cholesterol and blood cholesterol and human health and nutrition," "dietary calcium and its importance in human health and

nutrition;" and to recommend further studies to the Secretary. The delegation to the Assistance Secretary for Health excludes the authority to submit the report to the Congress.

Dated: July 21, 1986. S. Anthony McCann.

Assistant Secretary for Management and Budget.

[FR Doc. 86-17060 Filed 7-29-86; 8:45 am] BILLING CODE 4140-01-M

Centers for Disease Control

National Institute for Occupational Safety and Health; Test Protocol for Fibrous Aerosol Research; Open Meeting

The following meeting will be convened by the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control (CDC) and will be open to the public for observation and participation, limited only by the space available:

Date: August 13, 1986. Time: 9 a.m.-4 p.m.

Place: Room 203, 944 Chestnut Ridge Road, Morgantown, West Virginia 26505–2888.

Purpose: To discuss the research study protocol for the "Fibrous Aerosol Research" project. This project will evaluate the performance of particulate air-purifying respirator filters against a fibrous aerosol. Viewpoints and suggestions from industry, organized labor, academia, other government agencies, and the public are invited.

Additional information may be obtained from: Gregory A. Stevens, Division of Safety Research, NIOSH, CDC, 944 Chestnut Ridge Road, Morgantown, West Virginia 26505–2888. Telephones: FTS: 923–4335 Commercial: 304/291–4335.

Dated: July 22, 1986. Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 17057 Filed 7-29-86; 8:45 am]

Prevention Centers Grant Review Committee: Establishment

Pursuant to Federal Advisory Committee Act, 5 U.S.C. Appendix 2, the Centers for Disease Control announces the establishment by the Secretary of Health and Human Services, on July 25, 1986, of the following Federal advisory committee:

Designation: Prevention Centers Grant Review Committee.

Purpose: This Committee will provide advice and guidance to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, Centers for Disease Control, regarding the scientific merit and technical feasibility of grant applications relating to the establishment, maintenance, and operation of centers for research and demonstration with respect to health promotion and disease prevention.

Authority for this Committee will expire July 25, 1987, unless the Secretary of Health and Human Services, with the concurrence of the Committee Management Secretariat, General Services Administration, formally determines that continuance is in the public interest.

In order to conduct a fair review process of the grant applications and to meet the intent of Congress that the funds be awarded before the end of this fiscal year, it is imperative that this committee meet immediately—July 30—August 1, 1986. These are the only dates, within the time constraints that all or a quorum of the committee members will be available. Therefore, we were unable to meet the requirement for 15 days advance notice of establishment.

Dated: July 28, 1986. Elvin Hilyer,

Associate Director for Public Coordination. Centers for Disease Control.

[FR Doc. 86-17274 Filed 7-29-86; 8:45 am] BILLING CODE 4180-18-M

Prevention Centers Grant Review Committee; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), the Centers for Disease Control announces the following Committee meeting:

Name: Prevention Centers Grant Review Committee.

Dates: July 30-August 1, 1986.
Place: Auditorium A, Centers for Disease
Control, 1600 Clifton Road, NE, Atlanta,
Georgia 30333.

Time: 9:00 a.m.-5:00 p.m. Type of Meeting:

Open 9:00 a.m., 10:00 a.m., July 30, 1986 Closed 10:00 a.m., July 30-5:00 p.m., August 1, 1986

Contact Person: Steven D. Helgerson, M.D.; Executive Secretary of the Committee, Center for Professional Development and Training, Centers for Disease Control, Room 511B, Buckhead, 1600 Clifton Road, N.E., Atlanta, GA 30333, Telephones: FTS: 236-6701. Commercial: (404) 264-6701.

Purpose: This Committee is charged with advising the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, Centers for Disease Control, regarding the scientific merit and technical feasibility of grant applications relating to the establishment, maintenance, and operation of centers for research and demonstration with respect to health promotion and disease prevention.

Agenda: Agenda items for the meeting will include announcements, discussion of review procedures, and review of grant applications. Beginning at 10:00 a.m., Wednesday, July 30, through 5:00 p.m., Friday, August 1, the Committee will conduct its review of grant applications. This portion of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(6), Title 5 U.S. Code, and the Determination of the Director, Centers for Disease Control, pursuant to Public Law 92–463.

Agenda items are subject to change as priorities dictate.

In order to conduct a fair review process of the grant applications and to meet the intent of Congress that the funds be awarded before the end of this fiscal year, it is imperative that this committee meet on the above dates. July 30-August 1, 1986, are the only dates within the time constraints that all or a quorum of the committee members will be available to attend a committee meeting. Therefore, we were unable to meet the requirement for 15 days advance meeting notice.

Dated: July 28, 1986.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control. [FR Doc. 86–17273 Filed 7–29–86; 8:45 am] BILLING CODE 4160–18–M

Food and Drug Administration

Allergenic Products Advisory Committee: Renewal

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug
Administration announces the renewal
of the Allergenic Products Advisory
Committee by the Secretary of Health
and Human Services. This notice is
issued under the Federal Avisory
Committee Act of October 6, 1972 (Pub.
L. 92–463, 86 Stat. 770–776 (5 U.S.C. App.
II).

DATE: Authority for this committee will expire on July 9, 1988, unless the Secretary fomally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Richard L. Schmidt, Committee Management Office (HFA-306), Food and Drug Administation, 5600 Fishers Lane, Rockville, MD 20857, 301-443Dated: July 22, 1981.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-17042 Filed 7-29-86; 8:45 am]

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following consumer exchange meeting:

Dallas District Office, chaired by Gerald E. Vince, District Director. The topics to be discussed are Product Tampering, Irradiation of Foods, and Health Fraud.

ADDRESS: Texas Department of Health, 1401 South Rangerville Rd., Harlingen, TX 78552.

DATE: Friday, August 8, 1986, 9:30 to 11:30 a.m.

FOR FURTHER INFORMATION CONTACT: Juan A. Tijerina, Consumer Affairs Officer, Food and Drug Administration, 727 East Durango, Rm. B406, San Antonio, TX 78206, 512–229–6737.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's District Offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: July 22, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-17043 Filed 7-29-86; 8:45 am] BILLING CODE 4160-01-M

[Docket No. 85N-0583]

Low Back Referral Criteria Panel; Meeting

AGENCY: Food and Drug Administration. ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing a
forthcoming meeting of the Low Back
Referral Criteria Panel (the Panel). This
notice gives methods for interested
persons to submit written data and
views to the Panel, to participate in
open sessions of the meeting, and to
review the executive summary of
minutes of the meeting.

DATES: Open sessions: September 4, 8:30 a.m. to 9:30 a.m.; and September 5, 11:15 a.m. to 12 m.

ADDRESSES: The meeting will be held at the Holiday Inn Crowne Plaza Hotel in Rockville, MD. the executive summary of the minutes of the meeting may be reviewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jay A. Rachlin, Center for Devices and Radiological Health (HFZ-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4600.

SUPPLEMENTARY INFORMATION: Through the Center for Devices and Radiological Health, FDA conducts and supports research, training, and other activities to minimize unproductive radiation exposure from diagnostic radiological examinations. One possible source of unproductive radiation exposure is radiological examinations that are not likely to affect patient management. To minimize the number of requests for ineffective examinations, a referring physician needs to have up-to-date information about when a given radiological study is likely to provide needed diagnostic information. This information, which can take the form of decision guidelines based on patient signs, symptoms, or history, is termed here "referral criteria."

Under one part of a program designed to facilitate the development and testing by the medical profession of patient selection criteria for diagnostic radiological examinations, FDA is providing logistical support through a contractor for the convening of a small panel of clinical and scientific experts to formulate draft patient referral criteria or statements of use. A detailed description of the x-ray referral criteria development process was published in the Federal Register of June 9, 1981 (46 FR 30568).

This is the third meeting of the Panel. The meeting is being convened to review and edit the previous drafts of the acute low back imaging strategy for both adult and pediatric patients and to receive and review reports of the individual Panel members.

Interested persons may submit written data and views to the Panel. Any interested person who wishes to request time for oral presentations during the open sessions of the meeting should inform the contact person listed above, either orally or in writing, before the

meeting. Any person attending the meeting who does not request time in advance of the meeting date will be permitted to make an oral presentation at the conclusion of the open sessions, time permitting.

A list of committee members, the meeting agenda, and the executive summary of the minutes of the meeting may be reviewed at the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday. The final report will be available at the completion of the Panel's work. Materials will be filed under the docket number appearing in the heading of this notice.

Dated: July 22, 1981.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs. [FR Doc. 86–17044 Filed 7–29–86; 8:45 am] BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Intent To Prepare an Environmental Assessment on a Proposed Action To Recover Rare and Endangered Fish in the Upper Colorado River Basin

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: This notice advises the public that the Fish and Wildlife Service (Service) is preparing an environmental assessment on a proposed implementation program to recover four rare and endangered fish species in the Upper Colorado River Basin. This notice is being furnished in accordance with the CEO Regulations for implementing the National Environmental Policy Act (40 CFR 1501.7(b)(3)). We solicit public comment on impacts likely to result from the proposed action and alternatives, as well as suggestions on alternative means to protect and recover these fish species in a manner compatible with continued water development and State water allocation systems. Suggestions and information received will assist us in determining the scope of issues to be addressed and in evaluating their significance in the environmental assessment.

DATES: Written comments should be received by August 29, 1986.

ADDRESS: Comments should be addressed to: Regional Director, U.S. Fish and Wildlife Service, P.O. Box 25486, Denver Federal Center, Denver, CO 80225.

FOR FURTHER INFORMATION CONTACT: Barry Mulder, Chief, Office of Endangered Species, U.S. Fish and Wildlife Service, P.O. Box 25486, Denver Federal Center, Denver, CO 80225, (303) 236–7398, FTS 776–7398.

SUPPLEMENTARY INFORMATION:

I. Purpose and Need for Action

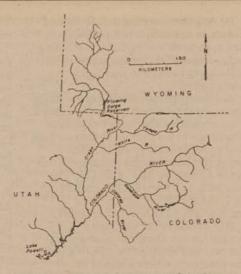
The purpose of the action is to protect and recover four rare fish species in the Upper Colorado River Basin in a manner that allows continued water development and that is consistent with State water rights systems, interstate compacts, and court decrees that allocate the rights to use Colorado River water among the States.

The four fish species of concern are the Colorado squawfish (Ptychocheilus lucius), humpback chub (Gila cypha), bonytail chub (Gila elegans), and razorback sucker (Xyrauchen texanus). The first three species are listed as endangered, and the fourth is a candidate for listing under the Endangered Species Act of 1973, as amended. The ultimate goal of the recovery implementation program is to delist the three endangered species and to manage the razorback sucker so it would not need the protection of the Endangered Species Act.

Though once abundant in the upper basin, these fish are now threatened with extinction. Their decline is attributed to a number of factors, ranging from habitat reduction or alteration to introduction of nonnative species. The Service has stated that continued water development within the upper basin is likely to further jeopardize these fishes' existence unless project impacts are offset by measures that preserve or improve these species' current status.

I. Affected Environment

The proposed action will occur in the Upper Colorado River Basin above Glen Canyon Dam, excluding the San Juan River. This area encloses the principal remaining habitat for the four fishes in the upper basin, as well as those waters (mainstem and tributaries) with potential to cause significant downstream impacts to the fish or their habitat. The affected area is located in Colorado, Utah, and Wyoming. (See map below)



III. Description of the Proposed Action and Major Alternatives

We invite public comment on impacts likely to result from the actions described below, as well as suggestions on alternative means to protect and recover the four rare and endangered fish species in a manner compatible with continued water development and State water allocation systems.

A Proposed Action

Preamble. The proposed action was developed by a subcommittee of the Upper Colorado River Basin Coordinating Committee. The Coordinating Committee is composed of representatives from the States of Colorado, Utah, and Wyoming; Bureau of Reclamation; Fish and Wildlife Service; private water development interests; and environmental organizations. The Department of the Interior is considering adopting their draft propsal for a cooperative Federal/ State/private program as the preferred means for resolving water use conflicts involving rare and endangered fish and water development action, as follows:

- 1. Administration. A Recovery Implementation Committee representing Federal, State, private water development, and conservation interests in the upper basin would oversee implementation of recovery actions for the four rare and endangered fish species. This committee would make recommendations to the Secretary of the Interior and the Staes, who would use their independent authorities to make and implement final decisions.
- 2. Recovery Timeframe. 15 years, estimated.
- 3. Recovery Actions—a. Habitat management.
- (1) Determine the locations, times, and quantities of instream flows needed to

protect and recover the fish and, through cooperation, prioritize work in this area.

- (2) Evalute alternative means for providing necessary flows. Once obtained, instream flows would be appropriated, acquired and administered under State law. Federal condemnation of water rights would not occur under the proposed action. Potental sources of water may include:
- (a) Allocating and releasing water from Federal storage projects. For example, through the section 7 consultation process, the Bureau of Reclamation would withhold from sale 5,000 acre-feet of water at Ruedi Reservior. This water would tentatively be released in the months of July-September, as needed.

(b) Refining operations at Federal reserviors. For example, the Bureau of Reclamation would refine operations at:

- (i) Ruedi Reservoir—would release an additional 5,000 acre-feet in the month of July-September on an average of 4 out of 5 years (supplementing the 5,000 acre-feet withheld from sale noted in A.3.a.(2)(a) above).
- (ii) Flaming Gorge Reservoir—until section 7 consultation is completed, has adopted an interim flow release schedule intended to improve rare and endangered fish spawning and survival. Ongoing research would determine a more permanent flow release pattern which would be outlined in the biological opinion planned to be completed in 1989.
- (iii) Blue Mesa Reservior—until section 7 consultation is completed, will release water to ensure that a 2,000 cubic feet/second minimum flow occurs below the confluence of the Gunnison and Colorado Rivers on an average of 9 out of 10 years. Research would determine a more permanent flow release pattern to be outlined in the completed biological opinion.
- (c) Purchasing or leasing existing water rights, on a willing seller basis, and converting these rights into instream flow rights.
- (d) Investigating the feasibility of acquiring "excess" water resulting from agricultural water conservation and salinity control projects and converting acquired water into insteam flows.
- (e) Investigating changing the point of diversion for senior water rights to downstream locations.
- (f) Investigating acquisition of nontributary ground water that could be pumped and put into streams.
- (g) Applying for original appropriation of instream flows in surface streams.
- (3) When section 7 consultation is conducted on future projects.

(a) The Secretary of the Interior would recommend reasonable and prudent alternatives, where possible, to offset nondepletion impacts of water projects jeopardizing the endangered fish, e.g., direct impacts caused by construction, inundation, or water quality changes resulting from reservoir operations.

(b) Since the proposed action establishes a commitment and mechanism to assure instream flows are acquired and protected under State law. the Service would consider these recovery actions as offsetting depletion impacts of most projects. Projects would be considered to have addressed depletion impacts by making contributions as described in A.4.c. below toward the recovery implementation program. However, if there are instances where project depletions are likely to jeopardize fish, the Service and Recovery Implementation Committee, where possible, would identify measures to offset these impacts, and implementation of these measures would be given immediate attention.

b. Habitate development and maintenance. The locations and degree to which any of the following techniques would be implemented would be determined after experimentation and consideration of effectivensss, cost, relationship to other recovery measures,

and secondary impacts.

(1) Create backwaters to enhance young-of-year fish production.

Backwaters can be created by manipulating river flow, connecting existing gravel pits/ponds to the river, or physically constructing backwaters.

(2) Increase spawning habitat by improving access to existing, unused spawning areas (e.g., fish passage structures), reintroducing eggs/larvae into suitable unoccupied habitat, modifying instream characteristics to create new spawning habitat, or constructing spawning habitat within the natural stream channel or in modified side channels.

(3) Create wintering habitat by

building jetties.

(4) Build fish passage facilities to reestablish Colorado squawfish in parts of their historic range, e.g., above Redlands Diversion Dam, Taylor Draw Dam, and Palisades.

c. Artificial propagation and stocking of rare and endangered fish species. (1) Use hatcheries as refugia to safeguard against disease and possible extinction.

(2) Raise fish in hatcheries and/or grow-out (rearing) ponds and use them

for basic research studies.

(3) Immediately introduce the bonytail chub, which appears in imminent danger of extinction in the upper basin.

(4) Augment existing populations of Colorado squawfish, humpback chub, and razorback sucker through stocking only after artificial propagation techniques have been thoroughly investigated.

d. Nonnative species and sportfishing management. Competiton and predation from nonnative species is believed to contribute to the decline of the four rare and endangered species. In addition, fishermen have caught endangered fish while seining for bait or angling. The following actions would be carried out by Federal or State agencies, as appropriate, to reduce future losses:

(1) Confine future stocking of nonnative fish shown to pose a threat to the rare and endangered fish to areas off the mainstem where absence of potential conflict with rare and endangered fish can be demonstrated.

(2) For nonnative fish shown to post a threat to the survival of rare and endangered fish, investigate the feasibility of selectively removing them from areas considered essential to the

latter species.

(3) Review sportfishing practices and regulations to reduce the likelihood of incidental take of rare and endangered fishers, e.g., permanent or seasonal closures of fishing areas where incidental take is a serious problem; prohibition of seining in spawning areas, young-of-year habitat, and juvenile nursery areas; restrictions on use of live bait.

(4) Implement an information and education program to educate the fishing public on rare and endangered fish.

e. Research, monitoring, and data management. (1) Implement a comprehensive research program to provide basic biological information on the fishes, to test management approaches, and to investigate institutional or administrative actions.

(2) Track the overall status and trends of rare and endangered fish populations within the upper basin with a monitoring program.

monitoring program.
(3) Establish a centralized data

management system.

4. Funding—a. Special Congress would be requested to establish two special funds:

(1) Water rights fund (\$10 million): Used to acquire water rights to secure instream flows for the rare and endangered fishes.

(2) Construction fund (\$5 million): Used for recovery actions involving capital expenditures, e.g., constructing hatchery or fish passage facilities, changing the point of diversion of a water right, or modifying habitat.

b. Annual. \$2.4 million would be provided yearly for recovery actions.

The Federal share would total \$2.1 million, and the States' share, \$300,000.

c. Intermittent. Private water developers would contribute a one-time amount of \$10/acre-foot (based on average annual depletion and adjusted annually for inflation) for new water depletion projects that have not yet complied with Section 7 of the Endangered Species Act. Contributions may also be made by conservation groups and private entities.

B. "No Action" Alternative—
Preamble. Since the Endangered Species
Act requires the Federal government to
protect and recover listed species, the
"No Action" alternative has been
construed to mean "status quo," i.e.,
continuation of current actions.

For example, Federal dams in the upper basin are required to comply constantly with section 7 of the Endangered Species Act. Dam operations must not jeopardize the survival of listed species and, where possible, should help conserve these species. These dams are being studied to determine if: (a) Water is available for instream flow needs and, (b) flow releases can be modified to increase production or survivorship of rare and endangered fishes. These actions would be implemented even if the proposed action is not adopted, and will be common to all alternatives under investigation.

(Note. These actions are denoted as recovery actions A.3.a.(2)(a) and A.3.a.(2)(b)

under the proposed action.)

The "No Action" alternative is as follows:

- 1. Administration. There would be no Federal/State/private oversight committee. Instead, the various agencies and developers would coordinate as needed on a project-by-project basis. The Service would review water projects through section 7 consultation and develop reasonable and prudent alternatives for projects likely to jeopardize endangered fish. The Bureau of Reclamation would ensure its projects are not likely to jeopardize the fish. The States would continue current efforts, as funds permit. It is presumed the States would not administer instream flows for the rare and endangered fishes.
- Recovery Timeframe. Indefinite (greater than 15 years).
- 3. Recovery Actions. The recovery actions outlined in the proposed action would take place as described, except as follows:
- a. Recovery actions that would not be undertaken due to lack of funds:
- (1) Nearly all water acquisition measures [A.3.a.(2)(c)-(g)].

(2) Construction of fish passage facilities at sites other than Redlands

Division Dam [A.3.b.(4)]

b. Recovery actions that would be undertaken, but at a slower pace than in the Proposed Action due to lack of funds:

(1) Determination of needed instream

flows [A.3.a.(1)].

(2) Creation of backwaters, spawning habitat, and wintering habitat [A.3.b.(1)-

(3) All artifical propagation and reintroduction efforts, except for maintenance of hatcheries as refugia [A.3.d.(1)-(4)].

(4) All nonnative species and sportfishing management efforts

[A.3.d.(1)-(3)].

(5) All research, monitoring, and data management efforts [A.3.e.(1)-(3)].

c. Recovery actions that would be substantively different from those in the

proposed action:

(1) For section 7 consultation, each project would be individually evaluated to determine the best mix of measures to offset impacts. In order to avoid jeopardy to the fish, project sponsors could be required to modify proposed structures, provide flows, and/or contribute funds for recovery implementation actions in some cases (per the existing depletion formula).

(2) The razorback sucker would likely be listed under the Endangered Species

Act.

(3) Releases from Federal reservoirs would not be legally protectd as

instream flow rights.

4. Funding. The existing level of funding would continue; i.e., approximately \$1.6 million annually would be directed toward recovering the rare and endangered fish, of which \$1.5 million would be Federal funds and \$100,000 would be State funds. Some money could continue to be contributed by water developers with small projects with correspondingly small depletions (See recovery action B.3.c.(1)).

C. "Federal Action Only"

Alternative—1. Administration. A

Recovery Implementation Committee
representing only Federal agencies
involved in Upper Colorado River Basin
resource management would use their
authorities and resources to recover the
fish. It is assumed that the States would
continue their current level of effort, as

funds permit.

2. Recovery Timeframe. Indefinite

(great than 15 years).

3. Recovery Actions. The recovery actions outlined in the proposed action would take place as described, except as follows:

a. Recovery actions that would be undertaken, but may proceed at a lower level of effort than in the proposed action due to the need for State cooperation and/or concurrence:

(1) Reintroduction efforts [A.3.d.(3),

[4]].

(2) Efforts to control nonnative fish species and sportfishing [A.3.d.(1)-(3)].

b. Recovery actions substantively different from those in theproposed

action:

(1) For section 7 consultation, each project would be individually evaluated to determine the best mix of measures to offset impacts. In order to avoid jeopardy to the fish, project sponsors could be required to modify proposed structures, provide flows, and/or contribute funds for recovery implementation actions. Under this alternative, project sponsors' contributions may be used to acquire water rights.

(2) If necessary, Federal condemnation of water rights would be considered to secure water for the fish.

(3) The razorback sucker could be listed under the Endangered Species Act.

c. Recovery actions that would be managed differently from those in the

proposed action:

(1) Overall, the Federal government would take a proportionately stronger role in determining and implementing recovery actions for the four fishes in

the upper basin.

(2) The Federal government will encourage the States to administer water rights (obtained as described in A.3.a.(2)(a)-(g)) under State water law. However, if the States do not agree to State administration, acquisition by the United States of instream flows under section 5 of the Endangered Species Act would be investigated. Assuming these flows could be legally protected, these instream flow rights would be held in the name of the United States, and administered by the States.

administered by the States.

4. Funding. The construction fund and annual funding levels would be equal to the Federal funding levels in the proposed action. Congress would be requested to authorize a water rights fund only if water acquired by the Federal government under section 5 of the Endangered Species Act could be protected as an instream flow right under State or Federal law. Private water developers could be requested to contribute toward recovery efforts as described in C.3.b.(1) above.

III. Impacts of the Proposed Action

Comments are invited on the direct, indirect, and cumulative impacts likely to result from implementing the proposed action and major alternatives. Areas of potential impact include:

A. Target species

- Federally listed species—Colorado squawfish, humpback chub, bonytail chub
- 2. Candidate species—razorback sucker

B. Nontarget species

1. Aquatic

a. Native fish species other than target species

b. Nonnative fish species

c. Sport fish species

2. Terrestrial

a. Sport species

b. Migratory birds

c. Endangered species

C. Recreation

- 1. Sportfishing
 - a. Reservoir
 - b. Stream
- 2. Rafting/Boating
- D. Electricity production
 - 1. Hydropower
 - 2. Nonhydropower
- E. Energy development
- F. Agricultural production
 - 1. Crops
 - 2. Livestock
- G. Municipal/Industrial
 - 1. Urban growth
 - 2. Industrial development
- H. Water quality
 - 1. Salinity
 - 2. Temperature
- I. Visual/aesthetic
- I. Historical/archaeological/cultural
- K. Land management agencies
- L. Habitats of Federal concern
 - 1. Floodplains
 - 2. Wetlands

A more detailed explanation of the proposed action may be obtained by calling or writing the contact person identified at the beginning of this notice.

The environmental review of this project will be conducted in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4371 et seq.), CEQ Regulations to implement NEPA (40 CFR Parts 1500–1508), other appropriate Federal regulations, and Department of the Interior and Service procedures for compliance with these regulations.

We estimate that the draft environmental assessment will be completed by September 1986.

Dated: July 23, 1986.

Galen L. Buterbaugh,

Regional Director.

[FR Doc. 86–17059 Filed 7–29–86; 8:45 am]

BILLING CODE 4310-55-M

Bureau of Land Management

[AA-56218]

Alaska Native Claims Selection; Cook Inlet Region, Inc.

In accordance with Departmental regulation 43 CFR 2650.7(d) notice is hereby given that a decision to issue conveyance under the provisions of section 14(e) of the Alaska Native Claims Settlement Act of December 18, 1971 (ANCSA), 43 U.S.C. 1601 1613(e), will be issed to Cook Inlet Region, Inc., for approximately 21 acres. The lands involved are within T. 1 S., R. 1 W., Fairbanks Meridian, Alaska.

A notice of the decision will be published once a week for four (4) consecutive weeks, in the Fairbanks Daily News-Miner. Copies of the decision may be obtained by contacting the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage Alaska 99513. ((907) 271–5960.)

Any party claiming a property interest which is adversely affected by the decision shall have until August 29, 1986 to file an appeal. however, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management, Division of Conveyance Management (960), address identified above, where the requirements for filing an appeal can be obtained. Parties who do not file an appeal in accordance with the requirements of 43 CFR Part 4, Subpart E shall be deemed to have waived their rights.

Olivia Short,

Section Chief, Branch of ANCSA Adjudication.

[FR Doc. 86–17115 Filed 7–29–86; 8:45 am] BILLING CODE 4310-JA-M

[AA-6661-C]

Alaska Native Claims Selection; Eklutna Inc.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of secton 14(a) of the Alaska Native Claims Settlement Act of December 18, 1971, (ANCSA), 43 U.S.C. 1601, 1613, will be issued to Eklutna, Inc., for approximately 1,733 acres. The lands involved are in the vicinity of Eklutna, Alaska.

Seward Meridian, Alaska

T. 15 N., R. 2 E. (Surveyed) T. 16 N., R. 2 E. (Surveyed) A notice of the decision will be published once a week for four (4) consecutive weeks, in the Anchorage Times. Copies of the decision may be obtained by contacting the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13 Anchorage, Alaska 99513. ([907] 271–5960.)

Any party claiming a property interest which is adversely affected by the decision shall have until August 29, 1986, to file an appeal. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management, Division of Conveyance Management (960), address identified above, where the requirements for filing an appeal can be obtained. Parties who do not file an appeal in accordance with the requirements of 43 CFR Part 4, Subpart E shall be deemed to have waived their rights.

Olivia Short,

Section Chief, Branch of ANCSA Adjudication.

[FR Doc. 86-17116 Filed 7-29-86; 8:45 am]

Iditarod National Historic Trail Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: The Iditarod National Historic Trail (INHT) Advisory Council will meet to advise the Secretary of the Interior, through the designated official, with regard to the implementation of a comprehensive management plan for the Iditarod National Historic Trail, Alaska.

Designated Official: Wayne A Boden, District Manager, Anchorage District Office, Bureau of Land Management.

Dates: September 8 and 9, 1986.

Place: Anchorage International Airport Inn, 333 W International Airport Road, Anchorage, Alaska.

Agenda

Monday, September 8, 1986

1:00 P.M.—Introductory Remarks 1:20 P.M.—Administrative Requirements 1:45 P.M.—INHT Advisory Council Charter 2:15 P.M.—Administrative History of the

INHT 2:45 P.M.-

2:45 P.M.—Break 3:00 P.M.—INHT Comprehensive

Management Plan Review
3:30 P.M.—Agency and Organization Reports
Bureau of Land Management
Fish and Wildlife Service
Forest Service
State of Alaska
Iditarod Trail Blazers
Others

Tuesday, September 9, 1986

8:30 A.M.—Election of Officers 9:00 A.M.—Public Testimony

10:30 A.M.—Break

10:45 A.M.—Summary of Issues

11:30 A.M.—Lunch Break

1:00 P.M.—Open Discussion and Resolutions 4:00 P.M.—Summary and Adjournment

Wayne A Boden,

Anchorage District Manager.

[FR Doc. 86-17117 Filed 7-29-86; 8:45 am]

BILLING CODE 4310-JA-M

INTERNATIONAL TRADE COMMISSION

Agency Form Submitted for OMB Review

In accordance with the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the Commission has submitted a proposal for the collection of information to the Office of Management and Budget (OMB) for review.

Purpose of Information Collection

The proposed information collection is a "generic clearance" under which the Commission can issue questionnaires for the following types of investigations: countervailing duty, antidumping, escape clause, escape clause review, market disruption and "interference with programs of the USDA."

Summary of Proposal

(1) Number of forms submitted: three.

(2) Title of forms: Sample Producer's, Sample Importer's and Sample Purchaser's questionnaires (i.e., the "samples" are an aggregate of the information that is likely to be collected in a series of questionnaires issued under the generic clearance).

(3) Type of request: extension.(4) Frequency of use: on occasion.

(5) Description of respondents: Businesses or farms that produce, import and/or purchase products under investigation.

(6) Estimated annual number of

respondents: 4,000.

(7) Estimated total annual number of hours to complete the forms: 100,000.

(8) Information obtained from the forms that qualifies as confidential business information will be so treated by the Commission and not disclosed in a manner that would reveal the individual operations of a firm.

Additional Information or Comment:

Copies of the proposed forms and supporting documents may be obtained from Debra Baker (tel. no. 202–523– 0284). Comments about the proposal should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attention: Ms. Francine Picoult). Any comments should be specific, indicating which part of the questionnaires or study plan are objectionable, describing the problem in detail, and including specific revisions or language changes.

Submission of Comments

Comments should be submitted to OMB within two weeks of the date this notice appears in the Federal Register. If you are unable to submit them promptly you should advise OMB within the two weeks period of your intent to comment on the proposal. Ms. Picoult's telephone number is 202–395–7231. Copies of any comments should be provided to Charles Ervin (United States International Trade Commission, 701 E Street, NW., Washington, DC 20436).

Hearing impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 724–0002.

Issued: July 25, 1986.

Kenneth R. Mason,

Secretary.

[FR Doc. 86-17096 Filed 7-29-86; 8:45 am]

[332-234]

Effect of Developing Country Debt Problems on U.S. Trade

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation.

EFFECTIVE DATE: July 23, 1986.

Background and Scope

The Commission instituted the investigation, No. 332–234, on July 23, 1986, under section 332(b) of the Tariff Act of 1930 (19 U.S.C. 1332(b)) at the request of the Subcommittee on Trade of the House Committee on Ways and Means. The purpose of the study is to examine the impact of the developing country debt situation, and debt-related austerity programs, on the U.S. trade balance.

As requested by the subcommittee, the study will examine the impact of developing countries' indebtedness on U.S. exports and export-related employment, as well as on imports from heavily indebted countries. The analysis will include an estimate of the sectoral impact of these developments.

FOR FURTHER INFORMATION CONTACT: Paul Golding, Office of Economics, U.S. International Trade Commission. Washington, DC 20436 (Telephone 202-523-1542).

Written Submissions

While there is no public hearing scheduled for this study, written submissions from interested parties are invited. Commercial or financial information which a party desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. To be assured of consideration by the Commission in this study, written statements should be submitted at the earliest practicable date, but no later than November 28, 1986. All submissions should be addressed to the Secretary, United States International Trade Commission, 701 E Street NW., Washington, DC 20436.

Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD termainal on 202–

724-0002.

Issued: July 24, 1986.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 86-17097 Filed 7-29-86; 8:45 am]

[Investigation No. 337-TA-252]

Heavy Duty Mobile Scrap Shears; Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 25, 1986, pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), on behalf of LaBounty Manufacturing, Inc., Industrial Site, State Road No. 2, P.O. Box B. Two Harbors Minnesota 55616. Supplements to the complaint were filed on July 11, 17, and 23, 1986. The complaint as supplemented alleges unfair methods of competition and unfair acts in the importation into the United States of certain heavy duty mobile scrap shears, and in their sale, by reason of alleged infringement of all

twenty-two claims of U.S. Letter Patent 4,519,135. The complaint further alleges that the effect or tendency of the unfair methods of competition and unfair acts is to destroy or substantially injure an industry, efficiently and economically operated, in the United States.

The complainant requests that the Commission institute an investigation and, after a full investigation, issue a permanent exclusion order and permanent ceases and desist orders.
FOR FURTHER INFORMATION CONTACT:

Deborah S. Strauss, Esq.,

OI

Gary Kaplan, Esq., Office of Unfair Import Investigation U.S. International Trade Commission, telephone 202– 523–1233 and 202–523–1088, respectively.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930 and in § 210.12 if the Commission's Rules of Practice and Procedure (19 CFR 210.12)

Scope of Investigation

Having considered the complaint, the U.S. International Trade Commission, on July 24, 1986, Ordered that:

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, an investigation be instituted to determine whether there is a violation of subsection (a) of section 337 in the unlawful importation into the United States of certain heavy duty mobile scrap shears, or in their sale, by reason of alleged infringement of all twenty-two claims of U.S. Letters Patent 4,519,135, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—LaBounty Manufacturing, Inc., Industrial Site, State Road No. 2, P.O. Box B, Two Harbors, Minnesota 55616.

(b) The respondents are the following companies, alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

The Dudley Shearing Machine
Manufacturing Co., Ltd., Nevada Lane,
Hot Lane Industrial Estate, Burslem,
Stoke-on-Trent, ST6 2BY England,
United Kingdom

Dudley Shearing, Inc., P.O. Box 18038, Charlotte, North Carolina 28218.

(c) Deborah S. Strauss, Esq., and Gary Kaplan, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 701 E Street NW., Room 126, Washington, DC 20436, shall be the Commission investigative attorneys, party to this investigation; and

(3) For the investigation so instituted, Janet D. Saxon, Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding administrative law judge.

Responses must be submitted by the named respondents in accordance with § 210.21 of the Commission's Rules of Practice and Procedure (19 CFR 210.21). Pursuant to § 201.16(d) and 201.21(a) of the rules (19 CFR 210.16(d) and 210.21(a)), such responses will be considered by the Commission if received not later than 20 days after the date of service of the complaint. Extensions of time for submitting responses will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings.

The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m., to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Room 156, Washington, DC 20436, telephone 202–523–0471. Hearing-impaired individuals are advised that information on this matter can be obtaining by contacting the Commission's TDD terminal on 202–724–0002.

Issued: July 25, 1986. By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 86-17098 Filed 7-29-86; 8:45 am]
BILLING CODE 7020-02-M

[Investigation No. 337-TA-226]

Mass Spectrometers and Components
Thereof; Commission Determination
on Review to Affirm an Initial
Determination Terminating
Investigation on the Basis of a
Consent Order; Issuance of Consent
Order

AGENCY: U.S. International Trade Commission.

ACTION: Determination on review to affirm an initial determination terminating the investigation on the basis of a consent order; issuance of a consent order.

SUMMARY: The Commission has determined on review to affirm the initial determination (ID) (Order No. 4) of the presiding administrative law judge (ALJ) terminatinig the above-captioned investigation as to respondents S.N. Nermag and Delsi, Inc., on the basis of a consent order.

FOR FURTHER INFORMATION CONTACT: Paul R. Bardos, Esq., Office of General Counsel, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436, telephone 202– 523–0350.

SUPPLEMENTARY INFORMATION: The authority for the Commission's disposition of this matter is contained in section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and 19 CFR 210.55 and 210.56. On May 2, 1986, the presiding ALI issued an ID granting the joint motion to terminate the investigation filed by complainant Finnigan Corporation and S.N. Nermag (Nermag) and Delsi, Inc., (Delsi), the respondents remaining in the investigation, on the basis of a consent order. On June 4, 1986, the Commission determined to review the ID and requested briefs from the parties on several questions relating to the proposed consent order. Complainant and the Commission investigative attorney filed briefs in response to the Commission's request.

Upon consideration of the briefs and the rest of the record in this investigation, the Commission has determined to affirm the ID and issue the proposed consent order. The Commission will, however, undertake enforcement of the consent order only with respect to products covered by the patent which was the subject of this investigation, and then only upon the termination of the license agreement between complainant and respondents as to that patent.

Termination of the investigation as to respondents Nermag and Delsi on the basis of the consent order furthers the public interest by conserving Commission resources and those of the parties involved.

Copies of the ALJ's ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436, telephone 202–523–0161. Hearing-impaired individuals are advised that

information on this matter can be obtained by contacting the Commission's TDD terminal on 202–724–0002.

Issued: July 21, 1986. By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 86-17099 Filed 7-29-86; 8:45 am] BILLING CODE 7020-02-M

Report to the President on Investigation No. TA-201-60, Steel Fork Arms

July 17, 1986.

Determination

On the basis of the information developed in the subject investigation, the Commission has determined that steel fork arms, provided for in item 692.40 of the Tariff Schedules of the United States, are not being imported into the United States in such increased quantities as to be a substantial cause of serious injury, or the threat thereof, to the domestic industry producing an article like or directly competitive with the imported article.

Background

The United States International Trade Commission instituted investigation No. TA-201-60 under section 201(b)(1) of the Trade Act of 1974 (19 U.S.C. 2251(b)(1)) to determine whether steel fork arms are being imported into the United States in such increased quantities as to be a substantial cause of serious injury, or threat thereof, to the domestic steel fork arm industry. This investigation resulted from a petition filed with the Commission on January 17, 1986, on behalf of the Ad Hoc Committee to Steel Fork Arm Producers. The Committee is constituted of the only two commercial producers of steel fork arms in the United States, Joseph Dyson & Sons, Inc. (Dyson), Painesville, OH, and GCN, Inc. (GCN), Seattle, WA. Steel fork arms are used on forklift trucks and similar lift equipment.

Notice of the institution of this investigation and the scheduling of a hearing was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the Federal Register of February 13, 1986 (51 FR 5420). The hearing was held on May 7, 1986, and all persons who requested the opportunity were permitted to appear in person or by counsel. The Commission announced its determination in this investigation in a public session on June 4, 1986, and

transmitted its report to the President on July 17, 1986. The information in the report was obtained from responses to Commission questionnaires, fieldwork and interviews by members of the Commission's staff, other agencies, information presented at the public hearing, briefs submitted by interested parties, the Commission's files, and other sources.

The view of the Commission are contained in USITC Publication 1866 (July 1986), entitled "Steel Fork Arms: Report to the President on Investigation No. TA-201-60 Under Section 201 of the Trade Act of 1974."

Issued: July 23, 1986. By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 86-17100 Filed 7-29-86; 8:45 am] BILLING CODE 7020-02-M

[332-232]

U.S. Global Competitiveness; the U.S. Automotive Parts Industry

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation.

EFFECTIVE DATE: July 9, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. Dennis Rapkins, Machinery and Equipment Division, Office of Industries, U.S. International Trade Commission, Washington, DC 20436 (telephone 202– 523–6299).

Background and Scope of Investigation

The Commission, on July 9, 1986, approved the institution of investigation No. 332–232, following receipt of letters on February 13, 1986, and April 2, 1986, from the Chairman of the Committee on Finance, United States Senate, requesting that the Commission conduct a series of investigations under section 332(b) of the Tariff Act of 1930 (19 U.S.C. 1332(b)) concerning the international competitiveness of a broad range of selected major United States industries. Institution of this study is scheduled for September 1, 1936.

The Commission investigation will examine the U.S. automotive parts industry and its major foreign competitors to determine the impact of global competition on the industry, and to assess how the industry is responding to these dynamic forces. As requested by the Committee, the Commission's report will analyze and address: (1) Measures of the current competitiveness of the U.S. industry in domestic and foreign markets; (2) comparative strengths of U.S. and major foreign

competitors in these markets: (3) the nature of major competitive problems facing the U.S. industry; (4) the sources of these problems, including the extent to which they arise from special transitory or reversible situations or are the result of more fundamental or structural problems; and (5) the importance of U.S. and foreign markets to the future competitiveness of U.S. and foreign producers, in terms of economies of scale, growth rates, and pre-empting of market advantages.

Public Hearing

The Commission will hold a public hearing on this investigation as well as the four others in this series requested by the Committee (investigation Nos. 332-229 through 332-233), at the U.S. International Trade Commission Building, 701 E Street, NW., Washington, DC, beginning at 10:00 a.m. on February 24, 1987. All persons shall have the right to appear in person or be represented by counsel, to present information and to be heard. Persons wishing to appear at the public hearing should file requests to appear and file prehearing briefs (original and 14 copies) with the Secretary, U.S. International Trade Commission, 701 E Street, NW., Washington, DC 20436, not later than noon, February 2, 1987. If the Commission decides to hold one or more hearings outside of Washington DC, it will issue a supplemental notice of hearing by January 16, 1987.

Written Submissions

Interested persons are invited to submit written statements concerning the investigation. Written statements should be received by the close of business on March 12, 1987. Commercial or financial information which a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary, United States International Trade Commission, 701 E Street, NW., Washington, DC 20436. Hearingimpaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 724-0002.

Issued: July 22, 1986.

By order of the Commission, Kenneth R. Mason,

Secretary.

[FR Doc. 86-17101 Filed 7-29-86; 8:45 am]

[332-230]

U.S. Global Competitiveness: Bullding-Block Petrochemicals and Competitive Implications for Construction, Automobiles, and Other Major Consuming Industries

AGENCY: United States International Trade Commission.

ACTION: Institution of Investigation.

EFFECTIVE DATE: July 9, 1986.

FOR FURTHER INFORMATION CONTACT: Eric Land or James P. Raftery, Energy and Chemicals Division, U.S. International Trade Commission, Washington, DC 20436, telephone (202) 523–0491 and 523–0453, respectively.

Background and Scope of Investigation

The Commission, on July 9, 1986, approved the institution of investigation No. 332–230, following receipt of letters on February 13, 1986 and April 2, 1986 from the Chairman of the Committee on Finance, United States Senate, requesting that the Commission conduct a series of investigations under section 332(b) of the Tariff Act of 1930 (19 U.S.C. 1332(b)) concerning the international competitiveness of a broad range of selected major United States industries.

The Commission investigation will examine the U.S. building-block petrochemical industry and its major foreign competitors to determine the impact of global competition on the industry and to assess how the industry is responding to these dynamic forces. As requested by the Committee, the Commission's report will analyze and address: (1) Measures of the current competitiveness of the U.S. industry in domestic and foreign markets; (2) comparative strengths of U.S. and major foreign competitors in these markets; (3) the nature of major competitive problems facing the U.S. industry; (4) the sources of these problems, including the extent to which they arise from special transitory of reversible situations or are the result of more fundamental or structural problems; and (5) the importance of U.S. and foreign markets to the future competitiveness of U.S. and foreign producers, in terms of economies of scale, growth rates, and pre-empting of market advantages. In addition, the Commission will examine the competitive implications of its findings

concerning the building-block petrochemical industry on such end-user industries as the automotive and construction industries.

Public Hearing

The Commission will hold a public hearing on this investigation as well as the four others in this series (Inv. Nos. 332–229 through 332–233) at the United States International Trade Commission Building, 701 E Street NW Washington, DC, beginning at 10:00 a.m. on February 24, 1987.

All persons shall have the right to appear in person or by counsel, to present information and to be heard. Persons wishing to appear at the public hearing should file requests to appear and should file prehearing briefs (original and 14 copies) with the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436, not later than noon, February 2, 1987. If the Commission decides to hold one or more hearings outside of Washington, DC, it will issue a supplemental notice of hearing by January 6, 1987.

Written Submission

Interested persons are invited to submit written statements concerning the investigation. Written statements should be received by the close of business on November 21, 1986. Commercial or financial information which a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary, United States International Trade Commission. 701 E Street NW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 724-0002.

Issued: July 22, 1986.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 86-17102 Filed 7-29-86; 8:45 am]

BILLING CODE 7020-02-M

[332-233]

U.S. Global Competitiveness: Optical Fibers, Technology and Equipment

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation.

EFFECTIVE DATE: July 9, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Johnson or Ms. Linda Linkins, General Manufactures Division, Office of Industries, U.S. International Trade Commission, Washington, DC 20436 (telephone 202–724–1730 or 202– 724–1745, respectively).

Background and Scope of Investigation

The Commission on July 9, 1986, approved the institution of investigation No. 332–233, following receipt of letters on February 13, 1986 and April 2, 1986, from the Chairman of the Committee on Finance, United States Senate, requesting that the Commission conduct a series of investigations under section 332(b) of the Tariff Act of 1930 (19 U.S.C. 1332(b)) concerning the international competitiveness of a broad range of selected major United States industries. Institution of this study is scheduled for September 10, 1986.

The Commission investigation will examine the U.S. optical fiber industry, and its major foreign competitors, to determine the impact of global competition on the industry, and to assess how the industry is responding to these dynamic forces. As requested by the Committee, the Commission's report will analyze and address: (1) Measures of the current competitiveness of the U.S. industry in domestic and foreign markets; (2) comparative strengths of U.S. and major foreign competitors in these markets; (3) the nature of major competitive problems facing the U.S. industry; (4) the sources of these problems, including the extent to which they arise from special transitory or reversible situations or are the result of more fundamental or structural problems; and (5) the importance of U.S. and foreign markets to the future competitiveness of U.S. and foreign producers, in terms of economies of scale, growth rates, and pre-empting of market advantages.

Public Hearing

The Commission will hold a public hearing on this investigation as well as the four others in this series (Inv. Nos. 332–229 through 332–233) at the United States International Trade Commission Building, 701 E Street, NW., Washington, DC, beginning at 10:00 a.m. on February 24, 1987. All persons shall have the right

to appear in person or be represented by counsel, to present information and to be heard. Persons wishing to appear at the public hearing should file requests to appear and should file prehearing briefs (original and 14 copies) with the Secretary, U.S. International Trade Commission, 701 E Street, NW., Washington, DC 20436, not later than noon, February 2, 1987. If the Commission decides to hold one or more hearings outside of Washington DC, it will issue a supplemental notice of hearing by January 16, 1987.

Written Submissions

Interested persons are invited to submit written statements concerning the investigation. Written statements should be received by the close of business on March 12, 1987. Commercial or financial information which a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's Rules of Practice and Procedure) 19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary, United States International Trade Commission, 701 E Street NW., Washington, DC 20436. Hearingimpaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 724-0002.

Issued: July 22, 1986.
By order of the Commission
Kenneth R. Mason,
Secretary.
[FR Doc. 86–17103 Filed 7–29–86; 8:45 am]
BILLING CODE 7020–02-M

[332-231]

U.S. Global Competitiveness: Steel Sheet and Strip Industry

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation.

EFFECTIVE DATE: July 9, 1986.

FOR FURTHER INFORMATION CONTACT: Ms. Nancy Flecher, Minerals and Metals Division, Office of Industries, U.S. International Trade Commission, Washington, D.C. 20436 (telephone 202– 523–0341).

Background and Scope of Investigation

The Commission on July 9, 1986, approved the institution of investigation No. 332–231, following receipt of letters on February 13, 1986, and April 2, 1986, from the Chairman of the Committee on Finance, United States Senate, requesting that the Commission conduct a series of investigations under section 332(b) of the Tariff Act of 1930 (19 U.S.C. 1332(b)) concerning the international competitiveness of a broad range of selected major United States industries. Institution of this study is scheduled for September 8, 1986.

The Commission investigation will examine the steel and strip industry and its major foreign competitors, to determine the impact of global competition on the industry, and to assess how the industry is responding to these dynamic forces. As requested by the Committee, the Commission's report will analyze and address: (1) Measures of the current competitiveness of the U.S. industry in domestic and foreign markets; (2) comparative strengths of U.S. and major foreign competitors in these markets; (3) the nature of major competitive problems facing the U.S. industry; (4) the sources of these problems, including the extent to which they arise from special transitory or reversible situations or are the result of more fundamental or structural problems; and (5) the importance of U.S. and foreign markets to the future competitiveness of U.S. and foregin producers, in terms of economies of scale, growth rates, and pre-empting of market advantages.

Public Hearing

The Commission will hold a public hearing on this investigation as well as the four others in this series (Inv. Nos. 332-229 through 332-233) at the United States International Trade Commission Building, 701 E Street, NW., Washington, DC beginning at 10:00 a.m. on February 24, 1987. All persons shall have the right to appear in person or be represented by counsel, to present information and to be heard. Persons wishing to appear at the public hearing should file requests to appear and prehearing briefs (original and 14 copies) with the Secretary, U.S. International Trade Commission, 701 E Street, NW., Washington, DC 20436, not later than noon, February 2, 1987. If the Commission decides to hold one or more hearings outside of Washington DC, it will issue a supplemental notice of hearing by January 16, 1987.

Written Submissions

Interested persons are invited to submit written statemens concerning the

investigation. Written statements should be received by the close of business on March 12, 1987. Commercial or financial information which a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's Rules of Practice and Procedure 19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary, United States International Trade Commission, 701 E Street, NW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 724-0002.

Issued: July 22, 1986.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 86-17104 Filed 7-29-86; 8:45 am] BILLING CODE 7020-02-M

[332-229]

U.S. Global Competitiveness: Textile Mill Industry

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation.

EFFECTIVE DATE: July 9, 1986.

FOR FURTHER INFORMATION CONTACT: Reuben Schwartz (202–523–0114) or Joseph Williams (202–523–5702), Textiles, Leather Products, and Apparel Division, Office of Industries, U.S. International Trade Commission, Washington, DC

Background and Scope of Investigation

The Commission, on July 9, 1986, approved the institution of investigation No. 332–229, following receipt of letters on February 13, 1986, and April 2, 1986, from the Chairman of the Committee on Finance, United States Senate, requesting that the Commission conduct a series of investigations under section 332(b) of the Tariff Act of 1930 (19 U.S.C. 1332(b)) concerning the international competitiveness of a broad range of selected major United States industries. Institution of this study is scheduled for September 2, 1986.

The Commission investigation will examine the U.S. textile mill industry and its major foreign competitors to determine the impact of global

competition on the industry, and to assess how the industry is responding to these dynamic forces. As requested by the Committee, the Commission's report will analyze and address: (1) Measures of the current competitiveness of the U.S. industry in domestic and foreign markets; (2) comparative strengths of U.S. and major foreign competitiors in these markets; (3) the nature of major competitive problems facing the U.S. industry; (4) the sources of these problems, including the extent to which they arise from special transitory or reversible situations or are the result of more fundamental or structural problems; and (5) the importance of U.S. and foreign markets to the future competitiveness of U.S. and foreign producers, in terms of economies of scale, growth rates, and pre-empting of market advantages.

Public Hearing

The Commission will hold a public hearing on this investigation as well as the four others in this series (Inv. Nos. 332–229 through 332–233) at the United States International Trade Commission Building, 701 E Street, NW., Washington, DC, beginning at 10:00 a.m. on February 24, 1987. All persons shall have the right to appear in person or be represented by counsel, to present information and to be heard. Persons wishing to appear at the public hearing should file requests to appear and prehearing briefs (original and 14 copies) with the Secretary, U.S. International Trade Commission, 701 E Street, NW., Washington, DC 20436, not later than noon, February 2, 1987. If the Commission decides to hold one or more hearings outside of Washington, DC, it will issue a supplemental notice of hearing by January 16, 1987.

Written Submissions

Interested persons are invited to submit written statements concerning the investigation. Written statements should be received by the close of business on March 12, 1987. Commercial or financial information which a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary. United States International Trade

Commission, 701 E Street NW., Washington, DC 20436. Hearingimpaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 724–0002.

Issued: July 22, 1986.

By order of the Commission.

Kenneth R. Mason.

Secretary.

[FR Doc. 86-17105 Filed 7-29-86; 8:45 am]

BILLING CODE 7020-02-M

INTERSTATE COMMERCE COMMISSION

[Docket No. AB-19 (Sub-121X]

The Baltimore and Ohio Railroad Co.; Exemption; Abandonment in Richland County, OH

AGENCY: Interstate Commerce Commission.

ACTION: Notice of Exemption.

SUMMARY: The Interstate Commerce
Commission exempts The Baltimore and
Ohio Railroad Company, Inc., from the
requirements of 49 U.S.C. 10903, et seq.,
to abandon its 17.75-mile line of railroad
in Richland County, OH, subject to
standard employee protective
conditions.

DATES: This exemption will be effective on August 29, 1986. Petitions to stay must be filed by August 11, 1986, and petitions for reconsideration must be filed by August 19, 1986.

ADDRESSES: Send pleadings referring to Docket No. AB-19 (Sub-No. 121X) to:

 Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

(2) Petitioner's Representative: Lawrence H. Richmond, 100 N. Charles Street, Baltimore, MD 21201.

FOR FURTHER INFORMATION CONTACT: Donald J. Shaw, Jr., (202) -275-7245.

SUPPLEMENTARY INFORMATION:

Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to T.S. InfoSystems, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423, or call 289–4357 (DC Metropolitan area), or toll-free 800– 424–5403.

Decided: July 22, 1986.

By the Commission, Chairman Gradison, Vice Chairman Simmons, Commissioners Sterrett, Andre, and Lamboley.

Noreta R. McGee,

Secretary.

[FR Doc. 86-17089 Filed 7-29-86; 8:45 am] BILLING CODE 7035-01-M

[Finance Docket No. 30867]

The Southern Michigan Railroad Society, Inc., Doing Business as Southern Michigan Railroad— Operation Exemption

The Southern Michigan Railroad Society, Inc., doing business as Southern Michigan Railroad (SMR), has filed a notice of exemption to operate ¹ a 13.45-mile line of railroad abandoned by Consolidated Rail Corporation. The line is a portion of the former Clinton Secondary Track, extending between milepost 0.25 and milepost 13.70 in Lenawee County, MI. Any comments must be filed with the Commission and served on Jeffrey Dobek, P.O. Box 434, Clinton, MI 49236, telephone [517] 456-7029.

The notice is filed under 49 CFR 1150.31. If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: July 24, 1986.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 86-17202 Filed 7-29-86; 8:45 am]

DEPARTMENT OF JUSTICE

Lodging of Consent Decree in U.S. v. Georgia-Pacific Corp.

In accordance with the policy of the Department of Justice, 28 CFR 50.7. notice is hereby given that on July 14, 1986, a proposed consent decree in United States v. Georgia-Pacific Corporation, Civil Action No. 85-1075, was lodged with the United States District Court for the Western District of Arkansas, El Dorado Division. This consent decree settles a lawsuit filed June 4, 1985, pursuant to section 113 of the Clean Air Act ("the Act"), 42 U.S.C. 7413, for injunctive relief and for assessment of a civil penalty against Georgia-Pacific Corporation ("Georgia-Pacific"). The complaint alleged, among other things, that Georgia-Pacific on at

least three occasions violated the applicable New Source Performance Standard ("NSPS") for the pollutant total reduced sulfur at a recovery furnace designated "8R" at Georgia-Pacific's kraft pulp mill in Crossett, Arkansas. The complaint alleged that Georgia-Pacific's violations of the emission standard constituted violations of section 111(e) of the Act, 42 U.S.C. 7411(e), and entitled the United States pursuant to section 113(b) of the Act, 42 U.S.C. 7413(b), to obtain a permanent or temporary injunction and recover a civil penalty of not more than \$25,000 per day of violation.

Under the terms of the proposed consent decree, Georgia-Pacific will undertake a program to attain and thereafter maintain compliance with the New Source Performance Standard for total reduced sulfur applicable to recovery furnace 8R, including: a trial period using water in the bottom of recovery furnace 8R's wet bottom precipitator, which period shall last no later than April 30, 1986; if Georgia-Pacific selects the use of water in the wet bottom precipitator as its permanent method of complying with the Act and the NSPS for total reduced sulfur, then Georgia-Pacific will demonstrate final compliance by June 20, 1986; if Georgia-Pacific does not select the use of water in the wet bottom precipitator as its permanent method of complying with the Act and the NSPS for total reduced sulfur, then Georgia-Pacific will install a dry bottom precipitator and demonstrate compliance using it by June 30, 1987. The proposed consent decree also calls for stipulated penalties against Georgia-Pacific for failure to meet the deadlines set by the decree or failure to meet the emission limitation for total reduced sulfur set by the decree. Also, the proposed decree calls for Georgia-Pacific to pay a civil penalty of \$35,000 with respect to the violations of the clean Air Act alleged in the complaint.

The Department of Justice will receive comments relating to the proposed consent decree for a period of 30 days from the date of this publication.

Comments should be addressed to the Assistant Attorney General of the Land and Natural Resources Division,

Department of Justice, Washington, D.C. 20530. All comments should refer to United States v. Georgia-Pacific Corporation, D.J. Ref. 90-5-2-1-781.

The proposed consent decree may be examined at the following offices of the United States Attorney and the Environmental Protection Agency ("EPA"):

¹ SMR's notice of exemption is for acquisition and operation of the line. However, because the line has been abandoned by Conrail [See Docket No. AB—187 (Sub-No. 154N), Conrail Ab. of the Clinton and Vulcan Secondary Tracks, MI (not printed), served March 1, 1982], no authority is needed for acquisition since the line no longer functions in interstate commerce. See Finance Docket No. 30641, Borinstein R.R. Co.—Exemption from 49 U.S.C. 10901 (not printed), served April 12, 1985.

EPA Region VI

Contact: Vicki R. Patton-Hulce, Office of Regional Counsel, U.S. Environmental Protection Agency, Region VI, 1201 Elm Street, Dallas, Texas 75270, (214) 767–9905

United States Attorney's Office

Contact: Larry McCord, Assistant United States Attorney, Western District of Arkansas, U.S. Post Office and Courthouse Building, 6th and Rogers Streets, Fort Smith, Arkansas 71801, (501) 740–3405

Copies of the proposed consent decree may also be examined at the Environmental Enforcement Section. Land and Natural Resources Division. United States Department of Justice, Room 1515, Ninth Street and Pennsylvania Avenue, NW., Washington, DC 20530. A copy of the proposed consent decree may be obtained by mail from the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice. In requesting a copy of the decree, please enclose a check for copying costs in the amount of \$1.60 payable to Treasurer of the United States.

F. Henry Habicht II,

Assistant Attorney General, Land and Natural Resources Divison. [FR Doc. 86–17024 Filed 7–29–86; 8:45 am] BILLING CODE 4410–01–M

Drug Enforcement Administration [Docket No. 86-31]

Yazid M. Mahdi, d/b/a Gresham Road Pharmacy; Revocation of Registration and Denial of Pending Applications

On March 24, 1986, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Yazid M. Mahdi (Respondent), trading as Gresham Road Pharmacy, of 2578 Gresham Road, Decator, Georgia 30316, proposing to revoke DEA Certificate of Registration AG2632986, and deny any pending applications for renewal of the registration as a retail pharmacy under 21 U.S.C. 823(f). The statutory predicate for the proposed revocation is that on August 30, 1985, in the United States District Court for the Northern District of Georgia, Yazid M. Mahdi, the proprietor and registered pharmacist of Greshan Road Pharmacy was convicted of violating 21 U.S.C. 841(a)(1) and 846, both felony offenses relating to controlled substances. On April 24, 1986, Respondent's counsel filed a request for

a hearing on the issues raised in the Order to Show Cause. Subsequent to filing the request for a hearing, Respondent's counsel notified the Hearing Clerk and Government counsel that Respondent wished to waive his right to a hearing. Therefore, the Adminitrator finds that Respondent has waived his opportunity for a hearing, and enters this final order based upon the record as it appears. 21 CFR 1301.54(d) and 1301.54(e).

The Administrator finds that during the Spring of 1985, the DEA Atlanta Field Division received information from a cooperated individual implicating Yazid M. Mahdi, the proprietor and pharmacis of Gresham Road Pharmacy. in the illegal sale of Didrex, a Schedule III controlled substance. According to the source, another individual was routinely traveling from Aiken, South Carolina to Decatur, Georgia to purchase commercial stock bottles of Didrex from Respondent, without a prescription, for the price of \$100.00 per 100 dosage units. The informant also told the investigators that the individual making the illegal purchases from the pharmacy would attempt to make another purchase on July 16, 1985. On that date, at approximately 7:45 p.m., a DEA Special Agent observed this individual entering the pharmacy. At that time a delivery truck also arrived at the pharmacy. The pharmacist, later identified as Yazid M. Mahdi, departed the pharmacy and within several minutes returned. The delivery truck departed shortly thereafter. According to the Special Agent, Mr. Mahdi went behind the pharmacy counter and handed the individual an object which was later to be identified as a white paper bag inscribed with the pharmacy name and containing ten pharmaceutical

bottles of Didrex with unbroken seals.

As as result of this transaction, Yazid M. Mahdi was arrested and charged with knowingly, intentionally, and unlawfully distributing a Schedule III controlled substance in violation of 21 U.S.C. 841. Following his arrest, and after having been advised of his rights, Mr. Mahdi spoke freely with Special Agents regarding his involvement in the illegal sale of Didrex on at least four occasions, including the incident which ultimately led to his arrest.

Subsequent to the investigation and his ultimate arrest, on July 19, 1985, the Georgia Board of Pharmacy suspended Mr. Mahdi's pharmacist's license through emergency suspension proceedings.

On August 30, 1985, in the United States District Court for the Northern District of Georgia, Mr. Mahdi pleaded guilty to one count of violation of 21 U.S.C. 841(a)(1) and 846, and one count of violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04. On November 1, 1985, Mr. Mahdi was sentenced to a period of six months incarceration for the first count, and was given a five year suspended sentence and placed on probation for a period of five years for the second. In addition, Mr. Mahdi was fined \$1,000.00, was ordered to perform 300 hours of community service, and was told that he could not apply for reinstatement of his pharmacy license during the probationary period.

Diversion Investigators also noted a severe shortage of Didrex while conducting a survey of prescriptions at Gresham Road Pharmacy. During a survey conducted in May, 1985, Mahdi informed Diversion Investigators that he purchased Didrex only from Bindley Western Drug Company, yet when questioned by Georgia Drug and Narcotics Agents on June 17, 1985, Mahdi claimed that his only supplier for Didrex was Harris Wholesale. He failed to inform the state agents that he also obtained Didrex from Bindley Western. A state audit conducted at Greesham Road Pharmacy for the period from April 1, 1985 to June 17, 1985, indicated a shortage of 2,450 dosage units of Didrex, or approximately 24 per cent of the pharmacy's stock. On July 25, 1985, DEA Diversion Investigators conducted an accountability audit for the pharmacy for the period from August 1, 1984 to July 16, 1985. The audit revealed a shortage of 15,789 dosage units of Didrex, which constitutes a 49.3 per cent shortage for this drug.

The Administrator notes that the pharmacy license for Gresham Road Pharmacy expired on June 30, 1985. The Georgia Board of Pharmacy gave the pharmacy the customary 90 day grace period to file for renewal. No such renewal was ever received by the Board. In February, 1986, the Board of Pharmacy sent a certified letter to the pharmacy concerning the expiration of its license; the letter was returned "non-delivery." Consequently, Gresham Road Pharamcy is no longer licensed by the Georgia Board of Pharmacy.

Based upon the facts discussed above, the Administrator concludes that there is a lawful basis for the revocation of the DEA registration for Gresham Road Pharmacy, and the denial of any pending applications for renewal. First, since neither Mr. Mahdi, nor the pharmacy itself, possess a valid state license, the Administrator cannot maintain the pharmacy's current DEA registration or grant an application for renewal of such registration. The Administrator has consistently held that

when a DEA registrant is not authorized to handle controlled substances in the state in which it operates, DEA is without lawful authority to maintain a registration. See *Diodo Leduc*, *d/b/a Farmacia Leduc*, Docket No. 85–5, 51 FR 12751 (1986); *Avner Kauffman*, *M.D.*, Docket No. 85–8, 50 FR 34208 (1985); *Kenneth K. Birchard*, *M.D.*, 48 FR 33778 (1983); *Thomas E. Woodson*, *D.O.*, Docket No. 81–4, 47 FR 1353 (1982).

Second, even had the pharmacy license not expired, Mr. Mahdi's felony convictions relating to controlled substances create a lawful basis for the revocation of Respondent's registration. DEA has consistently held that the registration of a corporate registrant may be revoked upon a finding that a natural person who is an owner, officer, or key employee, or who has some responsibility for the operation of the registrant's controlled substance busniess, has been convicted of a felony offense relating to controlled substances. See Ozie T. Faison, d/b/a Smith Discount Drugs, Docket No. 85-37, 51 FR 16403 (1986); Diodo Leduc, d/b/a Farmacia Leduc, supra.; Spoon's Pharmacy, Docket No. 84-42, 50 FR 46520 (1985); Daniel Levine, t/a Gladstone Pharmacy, Docket No. 84-20, 50 FR 32651 (1985); Coolidge Drugs, Inc., d/b/a/ The Apothecary, 50 FR 31785 (1985); Medicine Shoppe, 50 FR 30533 (1985); B. Ruppe Drugstore, Inc., Docket No. 84-16, 50 FR 23203 (1985); K & B Successors, Inc., Docket No. 82-15, 49 FR 34588 (1984). There is a lawful basis for the revocation of Respondent's registration and for the denial of any pending applications for renewal. 21 U.S.C. 824(a)(2). See Daniel Levine, t/a Gladstone Pharmacy, supra.; AG Pharmacy, Inc., Docket No. 79-12, 45 Fed. Reg. 6868 (1980); Serling Drug Co., Docket No. 74-12, 40 FR 11918 (1975); Rafael C. Cliento, M.D., Docket No. 79-2, 44 FR 30466 (1979).

The Administrator concludes that based on the facts and circumstances involved in this matter, the registration of Gresham Road Pharmacy should be revoked and any pending applications for renewal should be denied. The Administrator concludes that Mr. Mahdi has shown that he cannot be trusted to handle controlled substances. He ignored his professional obligations as a pharmacist when he chose to illegally dispense large quantities of dangerous controlled substances. Mr. Mahdi's control over Respondent pharmacy is too extensive to justify the continued registration of Gresham Road Pharmacy. The Administrator concludes that revocation of this pharmacy's registration is the only appropriate

sanction which will adquately protect the public interest.

Accordingly, having concluded that there are lawful bases for the revocation of Respondent's registration and for the denial of any pending applications for renewal, and having further concluded that under the facts and circumstances presented in this case, the registration should be revoked and all pending applications be denied, the Administrator of the Drug Enforcement Adminisration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b), hereby orders that **DEA Certificate of Registration** AG2632986, previously issued to Gresham Road Pharmacy, be, and it hereby is revoked. The Administrator further orders that any pending applications for renewal, be, and they hereby are denied.

This order is effective July 30, 1986.

Dated: July 24, 1986.

John C. Lawn,

Administrator. [FR Doc. 86–17021 Filed 7–29–86; 8:45 am] BILLING CODE 4410–09–M

Maurice L. Kaye, D.O.; Denial of Application for Registration

On November 8, 1985, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued to Maurice L. Kaye, D.O. of 735-47 49th Street North, St. Petersburg, Florida 33170 an Order to Show Cause proposing to deny his application executed on February 20, 1985, for registration as a practitioner under 21 U.S.C. 823(f). The statutory predicate for the proposed action was that: 1) On October 10, 1972, in the Pennsylvania Court of Common Pleas for Beaver County, Dr. Kaye was convicted of trafficking in prescriptions for contolled substances, prescribing controlled substances for known habitual users, and prescribing controlled substances without a physical examination, all felony offenses relating to controlled substances; 2) On March 29, 1973, in the Pennsylvania Court of Common Pleas for Beaver County, Dr. Kaye was convicted of unlawfully selling controlled substances to an undercover agent, failing to keep proper records for the sale of controlled substances, and unlawfully selling controlled substances without affixing a proper label to the container, all felony offenses relating to controlled substances; 3) On October 24, 1972, after Dr. Kaye failed to respond to an Order to Show Cause to revoke his registration in a timely manner, the

Bureau of Narcotics and Dangerous Drugs (the predecessor to the Drug Enforcement Administration) revoked his registration; 4) On March 25, 1985, the Florida Board of Osteopathic Medical Examiners revoked Dr. Kaye's license to practice osteopathic medicine in the State of Florida; 5) On August 6, 1985, in the Circuit Court of Pinellas County, Florida, Dr. Kaye was convicted of prescribing a controlled substance without a valid DEA registration, in violation of F.S. 893.13, a felony offense relating to controlled substances; 6) When Dr. Kaye executed his application for registration on February 20, 1985, he provided DEA with false information by indicating that he had never been convicted of a felony offense relating to controlled substances, that he had never been denied a CSA registration or had such registration revoked or suspended, when, in fact, he had been convicted of numerous felony offenses relating to controlled substances and had his registration both suspended and revoked in 1972; in addition, he answered "not applicable" to the question asking whether he was currently authorized to prescribe administer, dispense, or otherwise handle controlled substances under the laws of the state in which he intended to practice.

Dr. Kave did not request a hearing in response to the Order to Show Cause. Instead, he submitted a lengthy, largely incomprehensible, handwritten statement explaining his opposition to the proposed denial of his application for registration. In his handwritten statement, Dr. Kaye unsupportedly alleged that his DEA registration was never revoked. In addition, Dr. Kaye did not deny any of his numerous felony convictions relating to controlled substances. Rather, he simply attempted to argue that the numerous convictions were the results of actions taken by overzealous persons such as "a selfseeking district attorney, an aspiring judge, a lieing (sic), dishonest, crooked state drug bureau man, two dishonest state policemen, 2 croooked justices of the peace, 1 jealous social worker, several intolerant neighbors and one vengeful police chief . . ." In his statement, Dr. Kaye provided no information which would constitute mitigating factors for his actions. Therefore, Dr. Kaye's handwritten statement does nothing to support his application for registration and fails to adequately deny the charges outlined in the Order to Show Cause to deny his registration. Consequently, the Administrator finds no credence in Dr.

Kaye's statement and disregards such in evaluating this matter.

The Administrator concludes that Dr. Kaye is no longer licensed to practice medicine in the State of Florida. The investigative file indicates that on March 25, 1985, the Board of Osteopathic Medical Examiners of the State of Florida revoked Dr. Kaye's license to practice osteopathic medicine in the State of Florida. On April 3, 1985. Dr. Kaye filed an appeal to the Florida Department of Professional Regulation and the Board of Osteopathic Medical Examiners regarding the earlier revocation of his medical license. On April 26, 1985, the appeal was summarily denied. As a result of the revocation of his medical license, Dr. Kaye is no longer authorized to handle controlled substances in the State of Florida. The Administrator has consistently held that when an applicant for a DEA Certificate of Registration is not authorized to handle controlled substances in the state in which he seeks to operate, DEA is without lawful authority to approve the registration. See Emerson Emory, M.D., Docket No. 85-46, 51 FR 9543 (1986); and Marshall S. Tuck, M.D., Docket No. 80-28, 45 FR 85845 (1980). Thus, based on the revocation of Dr. Kaye's license to practice medicine in the State of Florida. apart from the other bases for denial. DEA is without the proper authority to register Dr. Kave.

Based on the extensive investigative file in this matter, the Administrator also finds that Dr. Kaye was indeed convicted of numerous felony offenses relating to controlled substances. On October 10, 1972, in the Pennsylvania Court of Common Pleas for Beaver County, Dr. Kaye was convicted of trafficking in prescriptions for controlled substance, prescribing controlled substances for known habitual users. and prescribing controlled substances without conducting a physical examination. As a result of his conviction on the three abovemethioned felony violations, Dr. Kaye was sentenced to serve a term of imprisonment of not less than three years, nor more than ten years. On March 29, 1973, in the Pennsylvania Court of Common Pleas for Beaver County, Dr. Kaye was convicted of three felony offenses arising out of his sale of controlled substances to undercover Pennsylvania State Police officers. As a result of this conviction, Dr. Kaye was ordered to pay a fine of \$3,000.00 and received a sentence of six months to one year incarceration. On August 6, 1985, in the Circuit Court for Penellas County, Florida, Dr. Kaye was convicted of

prescribing a controlled substance without a valid DEA registration. The evidence indicated that although Dr. Kaye's registration was revoked in 1972. he wrote a prescription for Dalmane, a Schedule VI controlled substance some thirteen years later, without the benefit of a reissued registration. As a result of this felony conviction, Dr. Kaye was placed on probation for a period of three years. In reviewing Dr. Kaye's numerous felony convictions relating to controlled substances, the Administrator finds that approval of Dr. Kaye's application for registration is clearly inconsistent with the public interest.

Further, the Administrator finds that Dr. Kaye materially falsified his application for registration executed on February 20, 1985. First, Dr. Kaye failed to disclose in his application that he was convicted of numerous offenses relating to controlled substances. Second. Dr. Kaye also failed to note that, based on his previous convictions, his registration had been revoked in 1972, and had never been renewed. Finally, Dr. Kaye failed to disclose required information regarding the status of his state medical license. Instead of properly answering whether he was properly licensed in the state in which he attempted to register, and include his current state medical license number, Dr. Kaye simply responded by claiming that the information requested was not applicable. Based on his numerous and egregious omissions of information on his application for a DEA Certificate of Registration, the Administrator concludes that Dr. Kaye clearly and materially falsified his application for registration.

In summary, based upon the extensive investigative file, the Administrator finds Dr. Kaye's application for registration cannot be approved since he is not currently licensed to practice medicine in the State of Florida. Additionally, based on his previous felony convictions relating to controlled substances and the material falsification of his application for registration, the approval of Dr. Kaye's application for registration would be wholly inconsistent with the public interest.

Accordingly, the Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) hereby orders that Dr. Kaye's application for a DEA Certificate of Registration, executed on February 20, 1985, be and is hereby denied.

This order is effective July 30, 1986.

Dated: July 24, 1986. John C. Lawn, *Administrator*. [FR Doc. 86–17022 Filed 7–29–86 8:45 am] BILLING CODE 4410–09–M

Office of Juvenile Justice and Delinquency Prevention

Missing Children's Assistance Act Program Priorities

AGENCY: Office of Juvenile Justice and Delinquency Prevention, Justice. ACTION: Notice FY 1986 Program Priorities for Missing Children's Act.

SUMMARY: Section 407 of the Missing Children's Assistance Act directs the Administrator to establish annual program priorities for making grants and contracts under section 406 of the Act.

The Administrator announced his proposed program priorities on May 10, 1985 and accepted public comments on these priorities for sixty days. On July 25, 1985 the Administrator published in the Federal Register a notice of final program priorities for the Missing Children's Assistance Act.

As directed by section 407 of the Missing Children's Assistance Act, the Administrator is announcing that Program Priorities for Fiscal Year 1986 are those which were announced for Fiscal Year 1985. No new program priorities will be established in this Notice for FY '86. All available funds will be used to fund the program priorities announced in the July 25, 1985 notice and those items mandated by Congress under section 404 of the Missing Children's Act.

DATE: Comments are due on or before September 29, 1986.

ADDRESS: Send comments to Verne L. Speirs, Acting Administrator, Office of Juvenile Justice and Delinquency Prevention, 633 Indiana Ave., NW., Washington, DC 20531 [202 724–7751.

FOR FURTHER INFORMATION CONTACT: Michelle Easton, Director, Missing Children's Program, Office of Juvenile Justice and Delinquency Prevention, 633 Indiana Ave., NW., Washington, DC 20531 (202 724–7655.

SUPPLEMENTARY INFORMATION:

Responsibility for establishing annual research, demonstration, and service program priorities for making grants and contracts pursuant to section 408 of the Missing Children's Assistance Act rests with the Administrator of the Office of Juvenile Justice and Delinquency Prevention. The Administrator is announcing that there are no new program priorities for making grants and

contracts pursuant to section 406 for FY 1986., FY 86 funds are also being used to fund the program priorities announced in FY 1985, and those activities mandated under section 404.

The Administrator is announcing his priorities and inviting public comments on these priorities for sixty days.

Section 406 Programs

Listed below are programs under section 406 of the Missing Children's Assistance Act which have been or we anticipate will be funded with FY'86 funds. These programs were announced in the July 25, 1985 Federal Register Notice of Final Programs Priorities. They

1. National Study of Law Enforcement Agencies' Policies and Practices Regarding Missing Children and Homeless Youth.

This study will describe current law enforcement policies and practices and identify the most effective law enforcement methods for handling reports and investigating, identifying and recovering children who may be missing or homeless and at risk of exploitation. It will also provide better estimates of the number of cases of missing children reported to law enforcement agencies annually.

2. The Child Victim as Witness Research and Development Program.

This study will design, implement and test new strategies to be used to improve court policies and practices for handling child victim witnesses.

3. Research on the Psychological Consequences of Abduction and Sexaul

Exploitation.

The primary goal of this research is to increase our knowledge of and develop effective treatment alternatives for the psychological consequences of families with missing and exploited children.

4. Training/Public Awareness

Program.

This will be a campaign of education and awareness on the missing children's

5. Assistance to State Clearinghouses for Missing and Exploited Children.

This program, run by the National Center for Missing and Exploited Children will solicit state applications for two-year awards that are intended to encourage states to develop clearinghouses and operate uniform data collection systems.

6. Assistance to Private Voluntary

Organizations.

This program run by the Institute for Non-Profit Organization Management, will award grants to expand the capacity of private voluntary organizations serving missing and exploited children.

Pursuant to section 404(a) and (b), the following programs were awarded with FY 1986 Missing Children's funds:

1. The National Center for Missing and Exploited Children to: a. Provide the information derived from the national toll free telephone line to appropriate law enforcement entities and to enable individuals to report information regarding the location of any missing child or other child 13 years of age or younger whose whereabouts are unknown to such child's legal custodians, and request information pertaining to procedures necessary to reunite such child with such child's legal custodian. (Section 404(a)(3) 404(b)(1))

b. Serve as a national resource center

and clearinghouse. (404(b)(2))

2. Institute for Non-Profit Organization Management (INPOM) to: Serve as a national resource center and clearinghouse focusing on assistance to private voluntary organizations working on the issue of missing and exploited children. (Section 404(b)(2)).

3. National Incidence Study (Pilot Studies): Funding of the first National Incidence Study is anticipated in FY 1987. Several pilot studies have been awarded to determine the merits of the various strategies available for conducting the National Incidence Study. (Section 404(b)(3).)

Dated: July 24, 1986

Verne L. Speirs

Acting Administrator, Office of Juvenile Justice and Delinquency Prevention. [FR Doc. 86-17032 Filed 7-29-86; 8:45 am]

BILLING CODE 4410-18-M

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Status of State Employment Security Administrative Financing Initiative and Opportunity to Comment on Elements for Long Term Change

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice and opportunity to comment on key elements in the State Employment Security Agency (SESA) administrative financing system.

SUMMARY: The Federal Register notice of December 20, 1985 (50 FR 51955) and January 3, 1986 (51 FR 264) announced a series of public meetings and requested comments on perceived problems and proposed solutions in administrative financing of the Federal-State Employment Security system. Oral and written comments from these meetings were summarized and published in the

Federal Register, March 14, 1986 (51 FR 8906). Additional review and analysis of these comments by State and Federal staff resulted in the adoption of shortterm changes (published in the Federal Register on May 16, 1986 (51 FR 18052)) and in the exploration of alternatives for long-term change. In this context, shortterm change is defined as actions which can be taken within the Department of Labor's administrative authority by Fiscal Year 1987. Long-term change is defined as actions which may require legislation or which cannot be implemented until Fiscal Year 1988.

Review of the various comments and proposals for change has identified ten elements critical to the shape of the administrative financing mechanism for the unemployment insurance (UI) system. Choices related to these principles or elements could provide the foundation for any change options.

This Federal Register notice describes each of the ten foundation elements and requests public comment on the degree of importance of each element in crafting long-term changes to the current administrative financing method.

After receiving these responses, the Secretary of Labor will evaluate the responses and develop proposals which will also be published in the Federal Register for comment. If this process results in any formal proposals for change to the UI administrative financing system, they all will be published in the Federal Register.

DATE: Written comments must be received by close of business on August 29, 1986, in order to be considered in the Secretary of Labor's evaluation of longterm changes.

ADDRESS: Submit written comments to Carolyn M. Golding, Director, Unemployment Insurance Service, **Employment and Training** Administration, 601 D Street, N.W., Washington, D.C. 20213.

FOR FURTHER INFORMATION CONTACT: Carolyn M. Golding, Director, Unemployment, Insurance Service, **Employment and Training** Administration, 601 D Street, N.W., Washington, D.C. 20213. Telephone: 202-

SUPPLEMENTARY INFORMATION:

376-6636.

Discussion of Key Elements in a Federal-State Unemployment Insurance Program

Review and analysis of the public comments to date have identified ten principles or elements as essential to the operation of a Federal-State unemployment insurance program. These key principles or elements are: (1) conformity and compliance; (2) monitoring/oversight; (3) flexibility; (4) productivityl; (5) objective data; (6) simplicity; (7) pooling-nonpooling; (8) tax collection; (9) distribution of the **Employment Security Administration** Account (ESAA) balance; and (10) borrowing for administration. In addition, four other issues are presented: presented: (1) the Federal Unified Budget and the Unemployment Trust Fund; (2) financing the cost of reimbursable employers; (3) carry forward of unobigated funds; and (4) fiscal year/program year.

For each of the ten elements, there is a range of possible choices as to the degree of centralization or decentralization for each element on a continuum from total Federal control to total State control. Along with these choices, there are also trade-offs. Each of these elements is described below including an indication of trade-offs which occur as choices are made for

more or less centralization. 1. Conformity and Compliance: Existing statutes comprise conformity and compliance requirements, including, for example, those requiring fair hearings, prompt and accurate payment of benefits, and immediate deposit of employer UI taxes into the Unemployment Trust Fund. Retaining these requirements means maintaining a substantial Federal oversight role in the UI system. Most commenters to date have suggested retaining the existing compliance and Federal Unemployment Tax Act (FUTA) requirements and the Secretary of Labor's role in ensuring that these requirements are met as a condition for continuing employer FUTA tax credits and certifying States to receive administrative grants. However, commenters have differed on how to measure and enforce these statutory

Under present law the Secretary of Labor acts as steward on behalf of the Federal government for administration of the requirements spelled out in the Federal Unemployment Tax Act (FUTA) and Title III of the Social Security Act (SSA). Other Federal laws, such as the Trade Act of 1974, and Titles IX, XI, and XII of SSA also affect the Federal-State

relationship.

requirements.

The major requirements in Title III of SSA are that benefits be paid in full when due through public employment offices, that opportunity for fair hearing be provided, that States deposit taxes immediately to the Secretary of the Treasury, that funds be withdrawn only for the payment of benefits with certain exceptions, that required reports be made, that certain information be disclosed to Federal agencies, that grant funds be expended only for purposes and in amounts found necessary by the Secretary, that States cooperate in the administration of Federal UI laws, and that interest be paid timely on Title XII advances, that certain information be furnished to Federally supported agencies and that States cooperate in the intercept of benefits, and that States also participate in the income and eligibility verification required by section 1137 of the SSA. If a State fails to meeet any of the requirements of Title III, the Secretary of Labor "shall make no certification for payment" of grants for administrative costs. Each requirement of Title III carries equal weight with respect to compliance.

FUTA requirements include the

(1) All compensation is to be paid through public employment offices or other approved agencies.

(2) Immediate deposit of unemployment fund receipts to

Secretary of Treasury.

(3) Withdrawal of money from fund only for payment of benefits with certain exceptions.

(4) "Labor standards."(5) "Coverage of employees of governmental entities and nonprofit organizations."

(6) Work since beginning of a benefit year in order to qualify for benefits in a succeeding benefit year.

(7) Benefits may not be denied to an individual who is in training with the approval of the State agency.

(8) Benefits may not be denied or reduced solely because the claimant is filing an interstate claim, and States must participate in wage-combining

(9) Benefits cannot be denied because of cancellation of wage credits except

for specified reasons.

(10) States must pay Extended Benefits (EB) in accordance with Federal-State Extended Unemployment Compensation Act of 1970.

(11) No person shall be denied benefits solely on basis of pregnancy or

termination of pregnancy.

(12) Benefits must be denied between sport seasons to professional althletes.

(13) State must deny benefits to

certain aliens.

(14) Benefits must be reduced by the amount of the pension and individual is receiving based on his/her previous

(15) States must provide wage information to Aid to Families with Dependent Children (AFDC) agencies.

(16) Any interest requested to be paid on Title XII advances shall be paid in a timely manner and must not be paid from the States' unemployment funds.

(17) Reservation of authority to amend or repeal State law at any time.

Failure to meet any of these requirements may result in noncertification by the Secretary of Labor and resultant loss of either administrative grants or the offset tax credit available to employers in States with certified States laws or both. (Currently, employers in a State may receive credit for up to 5.4 percent of the Federal unemployment tax due of 6.2 percent of taxable payrolls.)

Thus, any finding of nonconformity or noncompliance with Federal law is not one to be considered lightly. The purpose of the Federal-State unemployment insurance program, protection of unemployed workers and their communities from the ravages of unemployment, would not be accomplished if a State loses either the right of its employers of offset State taxes against FUTA taxes or its right to grants to cover costs of administration, either of which could, under current law, possibly lead to a collapse of the State

Accordingly, the statutes themselves spell out a series of steps protecting the rights of the States: notice to the State UI agency, notice to the Governor, right to administrative hearing and decision by the Secretary, and right of judicial review up to the United States Supreme Court. As a result, while negotiation of issues is frequent, satisfactory resolution virtually always results. On only two occasions during the 50-year history of the UI system has a State lost a portion of its Title III grants.

The Department engages in and requires considerable reporting and monitoring of State law, policy, and practice to measure and enforce conformity and compliance with Federal law. The Department accomplishes this through review of all State unemployment insurance laws, through annual measurement of program performance, through review of State Program and Budget Plans, through onsite evaluations, through periodic audits, and through other means.

While public comment to date indicates substantial agreement on the need to continue conformity and compliance requirements, disagreement has arisen as to whether all existing requirements should be retained, the methods by which these should be measured, and the enforcement measures which should be employed. In a highly decentralized system with minimal reporting and monitoring, measurement and enforcement would be much more difficult than in a more centralized system. If the choice is made

to seek repeal of Title III, SSA, Grants to States for Unemployment Compensation Administration, decisions would also need to be made on which, if any, of the Title III requirements should be moved to FUTA. (Repeal might occur as part of a change to transfer FUTA taxing authority and collection responsibilities to States.)

In this context response is sought on

the following questions:

(a) Which, if any, of the existing conformity compliance requirements in Title III of the SSA and the FUTA should be retained? Which should be repealed? What, if any, new requirements should be added?

(b) Should the Federal government periodically review State laws to insure conformity and compliance? State

policy? State practice?

(c) Should there be revisions to the current statutory sanctions specified in the event of nonconformity or noncompliance? If so, what should such revised sanctions be?

(2) Monitoring/Oversight: Generally, commenters have suggested that there is too much review and oversight by the Federal partner. This "monitoring" has

taken four forms:

(1) Advance approval of planned annual and quarterly spending (e.g., detailed, annual Program and Budget Plans (PBP) review and approval);

(2) On-site reviews of State performance of its major responsibilities

(e.g., EB reviews);

(3) Reports by States and the review and analysis of those reports (e.g., quality appraisal, quality control, claims workload reports, reports validation);

(4) After-the-fact audits of major activities. The monitoring efforts range from very detailed reviews of items of marginal significance to broader reviews of major activities.

Short-term changes have been implemented to reduce Federal oversight of financial activities. (For example, budget planning has been reduced from seven forms with 375 entries to two forms with 95 entries. Financial reporting has been reduced from 29 reports with almost 2000 entries to 10 reports with 470 entries. The actual number of reports will vary depending on the number of special programs, such as Disaster Unemployment Assistance, operating in a State.)

Analysis of spending trends and recapture of unobligated funds have been changed from a quarterly to annual frequency, increasing State flexibility to use granted funds during the year. Reporting of the use of UI resources has been greatly reduced and control of expenditures among program categories has been relaxed to bottom line only;

States may interchange resources among cost categories (e.g., salaries and nonpersonal services) and among program categories. Substantial reductions have occured in the amount of Federal control over financial management.

Remaining requirements include submission of an annual Program and Budget Plan, reporting of expenditure data (although vastly reduced), quarterly contingency rerporting, the annual quality appraisal process, quality control, workload reporting, validation of reports and auditing.

The short-term changes have not changed the level of Federal oversight of program activities or the measure of conformity and compliance. Adoption of any long-term changes would reduce

Federal oversight.

Prior public comments have indicated that monitoring/oversight should be reduced to the minimum necessary, without specifying what that minimum is. Defining the Federal role in measuring State performance in order to assess compliance under any changes to current system is essential if a Federal role in assuring conformity and compliance remains:

(a) Should Federal monitoring be limited to only ensuring that States meet conformity and compliance requirements? If so, should such monitoring be annual? More frequent? Less frequent? If not, what additional items should be monitored?

(b) Should the Federal government enumerate performance standards for each of the remaining conformity and compliance requirements?

(c) Should the Federal government be required to specify in advance all of its monitoring activities (including audits) as to frequency, items to be assessed, and level of detail?

(d) Alternatively, should the Federal government accept self-certification (e.g., by the governor) as evidence of a State's meeting conformity and compliance requirements?

3. Flexibility: Increased flexibility for States was one of the most frequently suggested solutions in public comments in January 1986 in response to excessive constraint and rigidity in the current system. Short-term changes to date would provide bottom line authority to the States for UI resources. However, bottom line authority between UI and Employment Service (ES) resources could exist only with legislative changes. Obviously, a system in which States collected and retained their own administrative tax would provide total flexibility in State use of these resources.

However, any State which had not raised sufficient administrative revenues would be required to generate additional revenue from increased employer taxes or some other source. State flexibility is less and Federal influence greater under any proposal in which the Federal government continues to collect FUTA taxes and allocate them to States, although an automatic pass-through mechanism could minimize Federal influence.

Financial flexibility over the use of administrative resources could be greatly increased in a system of State tax collection. Other choices made with regard to productivity, simplicity, pooling-nonpooling, and borrowing for administrative costs also affect the degree of flexibility—introducing constraints. If Federal requirements for meeting conformity and compliance remain, they also work to reduce flexibility in program administration.

Several questions arise regarding actions to increase State flexibility:

(a) Should a revised system of administrative finance include both the Wagner-Peyser (Employment Service) and Unemployment Insurance programs within a single funding mechanism?

(b) Should the States have "bottom line" authority on how to divide available funds betweens the Wagner-Peyser (Employment Service) and Unemployment Insurance programs?

(c) If States have total flexibility to switch resources between the Wagner-Peyser (ES) and UI programs, assessment of the need for additional UI claims processing resources would be more comlex as workloads rise and fall with changes in the business cycle. What State or Federal mechanisms could be used to ensure the availability of additional resources when claims workloads rise? For example, should a pass-through formula be indexed to changes in economic conditions if the Federal government continues to collect FUTA taxes?

(d) Total flexibility for resources used has implications for effective performance and for conformity and compliance. What restrictions, if any, should be applied to assure adequate performance beyond conformity and compliance? Only those to assure conformity and compliance? Should additional restrictions be added only if a State fails to meet requirements?

(e) Should existing performance standards be relaxed in order to allow greater State program flexibility? If so, under what conditions?

4. Productivity: Commenters have indicated that the existing administrative finance system contains

features which discourage productivity. For example, States are entitled to additional contingency resources to process increased workloads only to the extent that these resources are used. This "use or lose" feature results in some States either using more resources than needed to process increased workloads or not benefitting from savings produced by processing workload with fewer staff. Existing funding sytems do not recognized the principles of economy of scale or of minimum staffing. Moreover, when States achieve administrative cost reductions in unit times through improved procedures or automation, any savings thus realized are recaptured by the Federal government or redistributed among all States.

Potential changes to the system to encourage greater producitvity have been discussed. Among these is the establishment or expansion of fund sources from which States may draw to finance automation or other productivity-related projects including increasing the flow of funds under the

Reed Act.

Other proposals include increased accountability to the public within a State through greater and/or review of agency performance. Further management studies were suggested to determine national productivity factors.

There is a direct trade-off between flexibility and productivity. If States are given greater flexibility through bottom line responsibility, then productivity concerns are primarily a State responsibility as well. Productivity incentives or penalties, on the other hand, can work to reduce State flexibility. Productivity can also be affected by choices made on the conformity and compliance, simplicity, and pooling-nonpooling elements. Choices on those elements may create trade-offs adversely affecting productivity. Actions which impact productivity pose questions about overall resource management as indicated below:

(a) Is State productivity a State or a Federal concern? A joint one?

(b) Should productivity factors be a part of any administrative funding system or formula? If so, should States be financed using national producitvity measures without regard to individual State differences? Or on a State-by-State basis?

(c) If actions are taken by a State which reduce the cost of doing business, should the State retain some or all savings resulting from reduced costs? Should savings be recaptured to reduce overall system costs? Or employer taxes reduced?

(d) Should efforts be made by the Department of Labor to establish up-todate and accurate productivity data?

(e) Should there be a new "productivity improvement" or investment fund established? If so, under what conditions?

5. Objective Data: The use of objective, publicly available data in budget formulation and allocation is a factor which commenters have said should be considered.

In a totally decentralized system in which the States collected taxes for administrative financing, data for budget purposes would be totally a

State's decision.

In a system through which the Department of Labor determines and allocates resources, either an automatic pass-through or other basis, there must be advance definition of what type of data would be needed. The data requirements and formula could be stated in legislation or regulations. The term "objective data", as used by public commenters, also implied the use of a small number of data elements which could be derived easily and are readily available and verifiable. Commenters have stated that the UI budget included too many individual factors each with its own workload or formula for computation, and that this complexity obscured the understandability and availability of the data as well as their

Further response is needed to clarify the extent to which the use of objective, publicly available data are needed in the budget formulation and allocation process. The use of objective data is related to the simplicity issue. There are potentially adverse trade-offs between use of objective, predicitable and verifiable data and the system's responsiveness to changes in unemployment patterns over time and to State variations in productivity and cost. Choices made on this element may create positive or adverse impacts vis-avis productivity, conformity and compliance, and pooling-nonpooling.

Response to the following questions are sought to assist the Secretary in this

determination:

(a) To what extent should objective, readily available, verifiable data be used in budget formulation and allocation if its use would reduce the sensitivity of the budget to State differences and to changes in workloads and workload mix?

(b) Is it necessary for the budget formula to be fixed in regulation or statute in order to enhance availability and objectivity of the data?

(c) Should State share of FUTA contributions and State share of national unemployment be the principal factors in determining administrative funding levels? (There are objective, available and verifiable.)

(d) Should State relative productivity or cost of doing business be an element? (There are less objective, available and

verifiable.)

6. Simplicity: The public comment process disclosed the perception that the administraive financing process is too complex. Commenters suggested that improvements should be made to reduce the complexity. Suggestions included reduction of budget categories, reduction of contingency categories, reduction of planning and reporting requirements, and coordination of budget formulation and allocation so that the same processes are used for each.

Changes have already been made which reduce planning and reporting substantially. Contingency reporting for support costs has been simplified. Any options for long-term change would incorporate further simplification of Federal requirements for budget formulation, allocation and control.

Some of the complexity in the current system reflects an attempt to ensure fairness, equity, and the availability of additional funds when workloads exceed a certain baseline level. Actions which simplify the budget process may adversely affect perceptions of fairness, equity, and the system's ability to respond rapidly to increased workloads. Further response is needed on this issue to assist the Secretary to determine the optimum trade-off between simplicity and complexity. The following questions have been framed to elicit clarification:

(a) Should annual forecasts and variable workloads be retained as the major factor in the administrative financing formulas? Should it be strictly a State concern? A federal one? A joint one?

(b) Should the funding formulas be simplified to a small number of budget categories for unemployment insurance? To a single category? For ES and UI combined?

(c) Should there be a two-part process: formula funding for a baseline grant and additional funding for workloads above baseline? Should there be one formula allocation with carryover of unobligated resources from year-to-year forming a pool for workload increases in subsequent years?

(d) Should the budget process take into account State cost variables such as salary rates, degree of automation, workload levels, mix of workload, geographic and demographic

differences, organizational and operational differences, differences in State laws? What other factors should be included? What relative weights should these various factors have?

7. Pooling-Nonpooling: The current financing system collects its revenues through a flat tax on employers and distributes those revenues in the form of administrative resources based on forecast workload and unit costs of processing that workload. For a few States, administrative grants far exceed the taxes paid by their employers over time; for a few States, taxes and grants are roughly equivalent.

Pooling the tax revenues and distributing them based on workload amount to an insurance concept, pooling of risk/costs for administering the UI program. This has meant, in practice, that administrative funding could be adjusted quickly in response to workload shifts from State to State and from year to year with business cycle

changes.

Pooling also has also reflected the larger national economic environment within which State operate and which, frequently, is beyond their control or ability to anticipate. Pooling can adjust for the State employment impact from changes in: international demand for U.S. goods and services; nationwide economic conditions; and Federal government expenditure patterns.

State collection of revenues to support State administration would end pooling; taxes collected by a State from its employers would be the only source of revenue for costs of administerating that

State's ES and UI programs.

Suggestions have been made to establish an administrative loan fund for States which fail to raise adequate revenue for costs of administering that allocation system reflect some share of FUTA contributions made from each State. Many commenters felt that some form of pooled risk was necessary to insure the continuation of a national system of employment security.

Trade-offs exist between this element and flexibility, simplicity, productivity and conformity and compliance. These trade-offs would also reflect a shift in the locus of responsibility for many decisions between individual States and

the Federal government.

Additional response is needed to determine the extent to which the "pooled risk" concept should be retained in the administrative financing system. Several questions apply to this issue:

(a) Should "pooled risk" be retained as part of any administrative finance system? If so, what should be the extent of pooling, especially relative to the current system?

(b) Is it desirable to guarantee that each State has some minimum level of administrative resources to operate the employment security system? What should this minimum level reflect—employer FUTA contributions for a State? Other factors?

(c) Should the Federal government or State governments be primarily responsible for maintaining sufficient administrative funds to finance increased or variable workloads? Or should this be a joint responsibility?

(d) Should State allocations reflect some portion of FUTA contributions from each State? Should the appropriation include a minimum floor of FUTA receipts which would be appropriated and allocated?

8. Tax Collection: The FUTA tax is paid quarterly by employers to the Internal Revenue Service (IRS). The Department of the Treasury deposits an amount equal to FUTA receipts to the Unemployment Trust Fund and maintains accounts of receipts and disbursements within that fund.

For many years, various parties have advocated that the States should collect the FUTA tax, since the States collect the State unemployment insurance benefits taxes. The FUTA tax is used to pay for: Federal administration of the UI program; the Federal share of Extended Benefits; and Federal loans to States for benefit payments, as well as for State administration. These Federal functions would continue under any changes to State administrative financing and would require continued collection of an administrative tax for these purposes.

administrative tax for these purposes.

In any system of State collection of FUTA-type taxes, provision would have to be made for the annual certification by States to the IRS for individual employer eligibility for offset credit.

(a) Should long-term change include State collection of the FUTA tax? All of

it? Part of it?

9. Distribution of Employment Security Administration Account Balance (ESAA): Current law provides for retention in the ESAA of an amount equal to 40 percent of the prior year's appropriation from ESAA. This provision allows the account to maintain sufficient resources at the end of each fiscal year to finance administrative costs during the fall and winter months when workloads are high and FUTA receipts are low. (Of the 0.8 percent FUTA tax, 0.48 percent goes to ESAA and 0.32 percent to the Extended Unemployment Compensation Account (EUCA). Once the EUCA debt is repaid, the total rate will drop to 0.6 percent, but ESAA will receive 90 percent of the

total or 0.54 percent of FUTA.) The account is designed to also build cash balances during periods, of economic expansion to be available during periods of economic contraction. The balance at the end of Fiscal Year (FY) 1985 was \$1 billion, enough to finance 5 months of administrative cost at current workload levels or 4 months at recessionary levels. At the end of FY 1983, the account contained \$736 million, but 6 months later resources were exhausted. Treasury had to borrow \$124 million from general revenues in order to continue to finance State operations.

When the balance in ESAA reaches its statutory ceiling, surplus funds flow to the Extended Unemployment Compensation Account (EUCA). The EUCA is used to finance the Federal share of extended benefits and is currently in debt to general revenues by \$1.3 billion. Excess funds in the EUCA flow to the Federal Unemployment Account (FUA) to finance borrowing from States which have exhausted their State trust fund accounts. Currently the FUA owes general revenues of \$7.3 billion.

When all these ceiling are met and there are no outstanding balances owed by any account, excess funds flow to the Reed Act account from which they are disbursed to the State trust fund accounts. These amounts may be used for benefit payments or made available for administrative purposes through State appropriations. Once the existing debt for the Federal share of EB is repaid (anticipated in Calendar Year 1987), the Employment Security Administration Account will begin to develop large surpluses-exceeding what is needed for cash flow and high workload reserves.

One issue raised by public comment is what to do with these ESAA balances. If collection of the FUTA tax is transferred to States, at some point, a residual balance would be left in the ESAA of the Trust Fund. Disposition of this balance has been the subject of considerable discussion. Also, some commenters have questioned the level of funds maintained in this account currently. Two potential uses have been identified: (1) to pay transition costs for all States, or (2) to be retained as a source for future administrative loans to States.

(a) In a decentralized tax collection system, should ESAA residual balances be distributed to the States or retained in a loan fund? If distributed to the States, on what basis? (Should distribution be made on the same basis as Reed Act, i.e., in proportion to covered wages in each State?)

(b) If tax collection is retained as a Federal responsibility, should ESAA surplus balances be available for loans?

10. Borrowing for Administration: Suggestions have been made to establish a loan fund for administration. This fund could be used to provide capital for automation or for other administrative purposes.

Alternatively, if States collect FUTAtype taxes for administration, a loan fund may be essential to guarantee resources availability to States which did not raise sufficient revenues to operate an employment security program. Or, a loan fund could be provided strictly for the transition period as we move from the present system to a new administrative financing system.

Title XII of the Social Security Act provides a mechanism for States to borrow funds to pay benefits when State Trust Fund accounts are exhausted. This mechanism would continue under any contemplated revisions to the system.

The Reed Act distributes funds to States for the payment of benefits and for administrative expenditures when the Employment Security Administration Account (ESAA). **Extended Unemployment Compensation** Account (EUCA), and Federal Unemployment Account (FUA) reach their statutory ceilings. Acceleration of fund flow into Reed Act could be accomplished by lowering the statutory ceilings for the FUA, EUCA, and ESAA; however, such reductions in these accounts would have implications for fund solvency in future economic downturns.

An administrative loan fund would increase the resources available to States and increase the administrative costs to the Federal government. Establishing it would create trade-offs and affect the relationship among the elements of flexibility, monitoring, pooling-nonpooling, etc. It would reduce the availability of funds for distribution from the ESAA balance. It would also have an adverse impact on the Federal budget deficit.

Responses are needed to several clarifying questions:

(a) Should a loan fund be established for administrative funding?

(b) Should loans from this fund be available upon demand (subject to availability) or should the Federal government establish qualifying criteria? How should repayments be assured?

(c) Should the loan fund for administration be available even in times when the FUA and the EUCA have outstanding debts?

(d) Should the existing statutes be amended in order to accelerate the flow of funds within the fund so as to trigger a Reed Act distribution? If so, should the Reed Act account be used as the source of funds for a separate administrative loan account or should its proceeds be distributed to the States as under present statute?

(e) Should administrative loans be interest-bearing as the Title XII noncashflow loans are?

Other Issues for Comment

In addition to identifying these ten critical elements essential to operation of a national system of unemployment insurance, commenters suggested four other significant issues which are presented here for additional public

1. Federal Unified Budget and the Unemployment Trust Fund: This Fiscal Year 1969 Budget of the United States incorporated all trust funds held by the Federal government into the Unified Federal Budget. This change was made in order to improve the government's accounting for assets and liabilities and to provide a more accurate assessments of cash flow within the Federal budget. Public comments suggested removing the Unemployment Trust Fund from the Unified Federal Budget based on the perceived need to exempt budgeted resources in the fund from sequestering under the provisions of the Gramm-Rudman-Hollings Act. Since the fund cannot be used for any purpose beyond the employment security program, commenters argued that administrative funds from the Trust fund should not be subject to sequestering.

If the Unemployment Trust Fund were removed from the Unified Federal Budget, appropriation of resources from it for administrative costs would continue to be made by the Congress as was the case before the fund was incorporated into the Unified Federal Budget.

Likewise, the Congress could still impose sequestering on these administrative resources under the Gramm-Rudman-Hollings Act or other legislation as it did in FY 1986. Removal of the Unemployment Tust Fund from the Federal budget would have a onetime impact on the Federal deficit; the deficit would increase by the amount of the positive net balance in the fund. Even if the FUTA tax collection is transferred to the States, these taxes would still be in the Unified Federal Budget. They would simply be there as State collections, rather than Federal, as at present.

Further response is requested on the desirability of removing the Unemployment Trust Fund from the Unified Federal Budget:

(a) Should the Unemployment Trust Fund be removed from the Unified Federal Budget? Even if this action may have no impact on the appropriation of administrative resources?

2. Financing Administrative Costs of Reimbursing Employers: There is no provision in FUTA for taxes upon employers for services performed by employees of State and local governments and certain nonprofit organizations and agencies. Because of possible constitutional issues over Federal taxation of States and political subdivisions of States, the decision was made not to levy FUTA taxes on these governments but to require that State UI laws include employers and employees in covered employment. Although there was no constitutional issue with respect to nonprofit employers, the decision was made as a matter of public policy not to tax these but to enact a similar provision requiring State coverage These requirements were included in the **Employment Security Admendments of** 1970 (Pub. L. 91-373) in limited manner, and broadened in the Unemployment Compensation Amendments of 1976 (Pub. L. 94-566). Federal law requires that States must offer such employers the options either of paying State benefit costs under the standard provisions of State law or electing to reimburse the State on a dollar-for-dollar basis for the amount of benefits paid to former employees. Since these employers do not pay FUTA taxes, some portion of the taxes paid by employers taxed under FUTA (private sector employers in general) finances the costs of administration for these untaxed, reimbursing employers.

(a) Should provision be made in Federal law for reimbursing employers to pay administrative costs associated with claims filed by their former employees?

(b) Should a distinction be made between public entities and nonprofit entities for paying administrative costs? Should distinctions be made among nonprofit entities to differentiate between those which are charitable and others?

(c) Should Federal law provide for State option as to the collection of administrative costs from reimbursing employers?

3. Carry-forward of Unobligated Funds: The appropriation language for grants to States for unemployment insurance requires that normal budgetary adjustments be applied before using contingency funds. Thus, at year-end, any State unobligated funds must be recaptured and are not available to the carried forward to the

new fiscal year. By contrast, State unobligated Wagner-Peyser (Employment Service) grant funds may be permitted to be carried forward and expended in the succeeding two program years.

(a) Should provision be made in the appropriations acts to carry forward UI resources unobligated at the State level from the appropriation year into subsequent years? If so, for how long a

period?

4. Fiscal Year/Program Year: Under present appropriation language, administrative funds are provided for unemployment insurance on a fiscal year basis, whereas funds for administration of two related programs (Wagner-Peyser and the Job Training Partnership Act (JTPA)) are provided on a program year which begins July 1 and ends June 30.

State managers have pointed out that this diversity of budget periods has caused financial management problems

for them.

(a) Should administrative funds for unemployment insurance, Wagner-Peyser, ES reimbursables and JTPA grants be provided on a common budget year basis?

Responses to This Federal Register Notice

Responses should follow the outline set forth in the "elements" section of this Notice in order to facilitate summarization and presentation of the information. Respondents should address each question posed in the elements section. It would be helpful if respondents adhered to the numbering scheme set forth herein using element numbers and alphabetic designations for questions and responses.

Respondents may wish to offer additional comments or to propose other critical elements for consideration. Such additional response is encouraged and should be included following responses to the specific questions posed.

Signed at Washington, DC, on July 25, 1986. Roberts T. Jones,

Deputy Assistant Secretary of Labor. [FR Doc. 86-17198 Filed 7-29-86; 8:45 am] BILLING CODE 4510-30-M

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

Agency Information Collection Activities Under OMB Review

AGENCY: National Endowment for the Arts.

ACTION: Notice.

SUMMARY: The National Endowment for the Arts (NEA) has sent to the Office of Management and Budget (OMB) the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATE: Comments on this information collection must be submitted by August 14, 1986.

ADDRESSES: Send comments to Ms. Judy McIntosh, Office of Management and Budget, New Executive Office Building, 726 Jackson Place, NW., Room 3208, Washington, DC 20503; (202–395–6880). In addition, copies of such comments may be sent to Ms. Marianna Dunn, National Endowment for the Arts, Administrative Services Division, Room 203, 1100 Pennsylvania Avenue, NW., Washington, DC 20506 (202–682–5464).

FOR FURTHER INFORMATION CONTACT:
Ms. Marianna Dunn, National
Endowment for the Arts, Administrative
Services Division, Room 203, 1100
Pennsylvania Avenue, NW.,
Washington, DC 20506 (202–682–5464)
from whom copies of the documents are
available.

SUPPLEMENTARY INFORMATION: The Endowment requests the reinstatement of a previously approved collection for which approval has expired. The entry is issued by the Endowment and contains the following information: (1) The title of the form; (2) how often the required information must be reported; (3) who will be required or asked to report; (4) what the form will be used for; (5) an estimate of the number of responses; (6) an estimate of the total number of hours needed to prepare the form. This entry is not subject to 44 U.S.C. 3504(h).

Title: Theater Application Guidelines FY 1987/88.

Frequency of Collection: One-time. Respondents: Individuals, state or local governments, and non-profit institutions.

Use: Guideline instructions and applications elicit relevant information from individual artists, nonprofit organizations, and state or local arts agencies that apply for funding under specific Program categories. This information is necessary for the accurate, fair and thorough consideration of competing proposals in the peer review process.

Estimated Number of Respondents: 763.

Estimated Hours for Respondents to Provide Information: 17,595. Murray R. Welsh,

Director, Administrative Services Division, National Endowment for the Arts. [FR Doc. 86–17031 Filed 7–29–86; 8:45 am] BILLING CODE 7537-01-M

NUCLEAR REGULATORY COMMISSION

Applications and Amendments To Operating Licenses Involving No Significant Hazards Considerations; Bi-Weekly Notice

1. Background

Pursuant to Public Law (Pub. L.) 97-415, the Nuclear Regulatory Commission (the Commission) is publishing this regular bi-weekly notice. Pub. L. 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person-

This bi-weekly notice includes all amendments issued, or proposed to be issued, since the date of publication of the last bi-weekly notice which was published on July 16, 1986 (51 FR 25766) through July 21, 1986.

NOTICE OF CONSIDERATION OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE AND PROPOSED NO SIGNIFICANT HAZARDS CONSIDERATION DETERMINATION AND OPPORTUNITY FOR HEARING

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Comments should be addressed to the Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this Federal Register notice.

By August 29, 1986 the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the

Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that

the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission. Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to (Project Director): petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel-Bethesda, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board, that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1) (i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the local public document room for the particular facility involved.

Alabama Power Company, Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Unit Nos. 1 and 2, Houston County, Alabama

Date of amendments request: July 3, 1986.

Description of amendments request:
The amendments, as proposed, would change Technical Specifications
3.1.2.5.b.2 and 3.5.1.c by increasing the boron concentration limits by 300 ppm in the Refueling Water Storage Tank and in the reactor coolant system accumulators. The current boron limits would require the use of significantly more burnable absorbers in the design of the fuel for the next cycle. Therefore,

to achieve the necessary shutdown margin requirements for the accidents analyzed without more burnable absorbers, the licensee proposes to increase the existing boron limits.

Basis for proposed no significant hazards consideration determination: In Attachment 2 to the licensee's application, a significant hazards evaluation per 10 CFR 50.92 was provided. The licensee's analyses provides a detailed basis for their determination and concludes that the amendment involves a no significant hazards consideration. The licensee analysis is restated briefly as follows:

(1) Additional, unmodeled conservatism in LOCA and non-LOCA accident analyses will result,

(2) Additional shutdown capability has been added with no new failure modes introduced, and

(3) Increased boron provides added safety margin for accidents.

We have reviewed the licensee's analyses and agree. In addition, the Commission has provided guidance and examples of amendments that are considered not likely to involve significant hazards considerations. One example seems to fit the proposed change: example "(ii) A change that constitutes an additional limitation, restriction, or control not presently included in the technical specifications: for example, a more stringent surveillance requirement." The proposed Technical Specifications require maintenance of a boron concentration at 300 ppm greater than the existing limits. Since the increase in boron limits equates to a greater degree of shutdown margin than currently exists, the change requires additional boron and provides added assurance for maintaining reactor subcriticality at all times, when needed.

Therefore, on the basis of the licensee's analyses which we agree with and because the example seems to fit Example (ii) noted above, the Commission proposes that the amendment will not involve a significant hazards consideration.

Local Public Document Room location: George S. Houston Memorial Library, 212 W. Burdeshaw Street, Dothan, Alabama 36303.

Attorney for licensee: Ernest L. Blake, Esquire, 1800 M Street, NW., Washington, DC 20036.

NRC Project Director: Lester S. Rubenstein.

Arkansas Power and Light Company, Docket No. 50-313, Arkansas Nuclear One, Unit No. 1, Pope County, Arkansas

Date of amendment request: May 16, 1986.

Description of amendment request:
The amendment would correct a
typographic error in Technical
Specification Table 4.1–1, Item 43.a. Item
43.a deals with Instrumentation
Surveillance Requirements of the
Engineered Safety Actuation System
(ESAS) for switches and logic. The
symbol for the test surveillance was
originally "R" which denotes once every
18 months. The "R" was inadvertently
changed to "P" in a previous
amendment which did not deal with the
surveillance schedule of the ESAS.

Basis for proposed no significant hazards consideration determination: The Commission has provided guidance concerning the application of the standards in 10 CFR 50.92 by providing certain examples (51 FR 7750). An example of actions involving no significant hazards considerations is Example (i), an amendment involving a purely administrative change to technical specifications: for example, a change to achieve consistency throughout the technical specifications, correction of an error, or a change in nomenclature. The proposed Technical Specification modification corrects a typographical error in Table 4.1-1, Item 43.a and, therefore, falls within this example. Therefore, since the application for amendment involves a proposed change that is similar to the example for which no significant hazards considerations exist, the Commission has made a proposed determination that the application for amendment involves no significant hazards considerations.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Attorney for licensee: Nicholas S. Reynolds, Bishop, Liberman, Cook, Purcell and Reynolds, 1200 17th Street, NW., Suite 700, Washington, DC 20036. NRC Project Director: John F. Stolz.

Arkansas Power and Light Company, Docket No. 50-313, Arkansas Nuclear One, Unit No. 1, Pope County, Arkansas

Date of amendment request: May 21, 1986.

Description of amendment request:
The amendment would revise Technical
Specification section 3.4.1.3 and the
corresponding Bases. The proposed
change is required as a result of the
construction of a new seismic, partially
tornado protected, condensate tank
which will be dedicated to the
Emergency Feedwater System (EFW).
The proposed Technical Specification
will allow the required amount of
condensate to be stored in the new
seismic, partially tornado protected,

condensate storage tank. The amount of water to be required in the new tank is 107,000 gallons which corresponds to a depth of 11.1 feet. This number is based upon an amount of water to allow 4.5 hours of operation assuming average EFW flow. The decay heat removal system could be brought into operation within four hours or less. The transmitters at the new tank will be tornado protected and safety grade level indication will be provided in the control room.

Basis for proposed no significant hazards consideration determination: The proposed changes have been reviewed against each of the criteria in 10 CFR 50.92, namely that the proposed changes would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

With regard to (1) above, the new condensate storage tank will contain the same or a greater amount of water as the current condensate storage tank. In addition, the new tank will be seismic and partially tornado protected. Therefore, the proposed change of the storage of the required volume of water from the old tank to the new tank will not increase the probability or consequences of an accident previously analyzed.

With regard to (2) above, the new condensate storage tank will contain a volume of water equal to or greater than the volume of water required in the old condensate storage tank. Also, the hookup to the EFW pumps from the new tank will be as reliable as the hookup from the old tank due to the use of locked open manual valves in the flow path from the new tank. Thus, this change does not create the possibility of a new or different kind of accident.

With regard to (3) above, unlike the current condensate tank, the new condensate tank is seismically qualified and partially tornado protected.

Therefore, this proposed change would not reduce the margin of safety.

On these bases, the Commission proposes to determine that the proposed amendment does not involve a significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Attorney for licensee: Nicholas S. Reynolds, Bishop, Liberman, Cook,

Purcell and Reynolds, 1200 17th Street, NW., Suite 700, Washington, DC 20036. NRC Project Director: John F. Stolz.

Commonwealth Edison Company, Docket No. STN 50-454 Byron Station. Unit 1 Ogle County, Illinois

Date of application for amendment: November 26, 1985, supplemented June

Description of amendment request: The amendment would revise the Technical Specification section 3/4.5.2 to allow closure of either of the Residual Heat Removal (RHR) Pump discharge to Reactor Coolant System (RCS) cold leg isolation valves (SI8809A and SI8809B). along with the Safety Injection Pump discharge to RCS cold leg valve (SI8835). in order to perform certain check valve back leakage testing.

Technical Specification 4.4.6.2.2 requires that check valves in the accumulator cold leg injection lines must be checked during specific periods for back leakage into the RHR system. If valves SI8835 and either SI8809A or SI8809B are not closed during this testing, other systems could leak into the check valve test lines causing false reading of check valve leakage and, if check valve leakage is detected, it would be more difficult to determine which valves are leaking.

It is the staff's intention to apply this amendment to Byron Station, Unit 2, when it receives its operating license if the amendment is found acceptable for

Byron Station, Unit 1.

Basis for Proposed No Significant Hazards Consideration Determination: Based on the three criteria in 10 CFR 50.92 for defining a significant hazards consideration, operation of Byron Station, Unit 1, in accordance with the proposed amendment will not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated. The probability of an accident previously evaluated remains unchanged since the proposed change only involves closure of two valves for short periods of time. The consequences of an accident previously evaluated will not be significantly increased because the accident was previously evaluated for operation in Mode 1.

The proposed change will only be authorized for operation in Mode 3. The corresponding lower initial fuel temperatures in Mode 3 will result in less severe consequences than

previously evaluated.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated because the change only allows closure of two valves for short periods of time.

(3) Involve a significant reduction in a margin of safety because the margin of safety is determined by an analysis assuming Mode 1 operation at the time of the accident. As previously stated, the proposed change is restricted to Mode 3 operation which results in less severe consequences than Mode 1 operation. Therefore, the staff proposes to determine that the amendment does not involve a significant hazards consideration.

Local Public Document Room location: Rockford Public Library, 215 N. Wyman Street, Rockford, Illinois 61103.

Attorney for licensee: Michael Miller, Isham, Lincoln & Beal, One First National Plaza, 42nd Floor, Chicago, Illinois 60603.

Commonwealth Edison Company, Docket No. 50-249, Dresden Nuclear Power Station, Unit No. 3, Grundy County, Illinois

Date of amendment request: June 18, 1986.

Description of amendment request: The proposed changes to the Technical Specifications (TS) involve modifications to the surveillance requirements for the following Reactor Protection System and Emergency Core Cooling System instruments due to the replacement of these instrument channels with an Analog Trip System:

(1) Reactor low-low water level. (2) Reactor low water level.

(3) High pressure coolant injection (HPCI) high steam flow.

(4) HPCI steam line low pressure. The changes affect TS tables, notes and bases that pertain to the above instruments.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards determination exists as stated in 10 CFR 50.92(c).

The licensee has presented its determination of no significant hazards

consideration as follows:

Commonwealth Edison has performed an evaluation of the hazards consideration associated with the proposed Technical Specification amendments utilizing the criteria of 10 CFR 50.92. Our evaluation is provided below and specifically addresses the three criteria of 10 CFR 50.92(c)

The proposed amendments do not involve a significant increase in the probability of or consequence of an accident previously evaluated because the new Analog Trip System will be tested at surveillance intervals deemed adequate to maintain the integrity of the monitoring systems while at the same time eliminating the possibility for the

same failure mechanisms as the existing instrumentation. Changes to the surveillance intervals will not prevent the Analog Trip System from functioning the same, or causing the same actions as the instrumentation being replaced.

The proposed amendments do not create the possibility of a new or different kind of accident from any accident previously evaluated because the function of the replacement transmitter/trip units remains unchanged by the new surveillance requirements. The new instrumentation has demonstrated greater reliability than that being replaced and the new surveillance requirements ensure that adequate availability of the Analog Trip System is maintained.

The proposed amendments do not involve a significant reduction in a margin of safety because most failures resulting from the primary sensor (transmitter) are detected by the trip units themselves which are subjected to a once per month surveillance interval. This interval is consistent with and as conservative as previous surveillance intervals for calibrating/testing. Redundant transmitters allow outputs to be compared, further minimizing any undetected failures.

For the reasons stated above Commonwealth Edison finds that the proposed amendments do not involve a significant hazards consideration based on the criteria of 10 CFR 50.92(c)

The staff has reviewed the licensee's no significant hazards consideration determination and the technical content of the submittals and agrees with the licensee's analysis. In addition, the staff notes that an identical amendment request for Dresden Unit 2 was similarly noticed on November 21, 1984 (49 FR 45945). Based on this, the staff has made a proposed determination that the requested amendment involves no significant hazards consideration.

Local Public Document Room location: Morris Public Library, 604 Liberty Street, Morris, Illinois 60450.

Attorney for licensee: Mr. Michael I. Miller; Isham, Lincoln and Beale, Three First National Plaza, Suite 5200, Chicago, Illinois 60602.

NRC Project Director: John A. Zwolinski.

Commonwealth Edison Company, Docket No. 50-374, La Salle County Station, Unit 2, La Salle County, Illinois

Date of amendment request: June 11, 1986.

Description of amendment request: The proposed amendment to Operating License NPF-18 would revise the La Salle Unit 2 Technical Specifications

because the eight 26-inch and two 8-inch vent and purge isolation valves are being replaced by Clow Corporation made valves which meet all the requirements for containment vent and purge isolation valves. Since the new valves are qualified to close from any position including the full open (90°) position, Technical Specifications 3.6.1.8, 4.6.1.8 and associated basis 3/ 4.6.1.8 must be revised to remove the 50° limit on valve opening. This limit was required until these valves could be replaced by valves capable of closing during a postulated loss-of-coolant accident or a steam line break. In addition, the new valves do not contain resilient seals. As a result, the once per 92 days leakage surveillance is no longer required since the purpose of the accelerated leakage rate testing (every 92 days) was to provide an early indication of resilient material seal degradation.

In addition, as required by License Condition 2.C.(8), these new valves will not require AC power to operate; they are air operated. Therefore, as there is no thermal overload bypass function required, the licensee has requested deleting these valves from Technical Specification Table 3.8.3.3-1. Also, the new valves will meet the 10 second closure time required by License Condition 2.C.(8); and the "**" notation on Technical Specification Table 3.6.3-1, permitting a 40 second closure time is

being deleted.

The above items addressed in this proposed amendment and these modifications will be incorporated at the first refueling outage in accordance with License Condition 2.C.(8).

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92 (c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has determined, and the NRC staff agrees, that the proposed amendment will not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated because the new vent and purge isolation valves are replacing the current isolation valves. The new valves meet the requirements for vent and purge containment isolation valves. This amendment removes requirements which only apply to the valves being removed.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated because the modification does not affect the containment isolation valve arrangement.

(3) Involve a significant reduction in the margin of safety because the design continues to meet the requirements of General Design Criterion 56, as specified in the updated Final Safety Analysis

Report.

Accordingly, the Commission proposes to determine that the proposed changes to the Technical Specifications involve no significant hazards considerations.

Local Public Document Room location: Public Library of Illinois Valley Community College, Rural Route No. 1, Ogelsby, Illinois 61348.

Attorney for licensee: Isham, Lincoln and Burke, Suite 840, 1120 Connecticut Avenue, NW., Washington, DC 20036. NRC Project Director: Elinor G.

Adensam.

Commonwealth Edison Company, Docket No. 50-374, La Salle County Station Unit 2, La Salle County, Illinois

Date of amendment request: July 3, 1986.

Description of amendment request: The proposed amendment to Operating License No. NPF-18 would revise the La Salle Unit 2 Technical Specifications to reflect the alternative logic modification of the automatic depressurization system (ADS) as required by License Condition 2.C.(18)(d). This requirement is described in Supplement 5 to the La Salle Safety Evaluation Report which indicated that the proposed modifications would be acceptable following: 1) approval by the NRC staff of the detailed logic implementation; 2) the submittal of a plant specific analysis to justify the bypass timer setting; 3) the submittal of Technical Specifications for the use of the bypass timer and manual inhibit switch; 4) modification of plant emergency procedures to address the use of the inhibit switch; and 5) completion of the modifications prior to startup after the first refueling.

The above items are addressed in this proposed amendment and this modification will be incorporated at the first refueling outage.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92 (c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has determined and the NRC staff agrees that the proposed amendment will not:

- (1) Involve a significant increase in the probability or consequences of an accident previously evaluated because the revised ADS logic does not affect automatic depressurization for events where high drywell pressure occurs. This modification automates the function of reactor vessel blowdown for events where high drywell pressure does not occur. Under these conditions, manual operation of the ADS system is called for by the emergency operating procedures and was assumed in Chapter 15 of the Final Safety Analysis Report.
- (2) Create the possibility of a new or different kind of accident from any accident previously evaluated because automatic depressurization is analyzed and required for events where high pressure coolant sources are unavailable and reactor vessel level is low. This change only automates what were previously manual operator actions.
- (3) Involve a significant reduction in the margin of safety because the upgraded logic provides additional margin of safety for events where high drywell pressure does not occur while still providing the same level of protection for events where high drywell pressure does occur.

Accordingly, the Commission proposes to determine that the proposed change to the Technical Specifications involves no significant hazards considerations.

Local Public Document Room location: Public Library of Illinois Valley Community College, Rural Route No. 1, Ogelsby, Illinois 61348.

Attorney for licensee: Isham, Lincoln and Burke, Suite 840, 1120 Connecticut Avenue, NW., Washington, DC 20036.

NRC Project Director: Elinor G. Adensam.

Commonwealth Edison Company. Docket No. 50-374, La Salle County Station Unit 2, La Salle County, Illinois

Date of amendment request: July 3, 1986.

Description of amendment request: The proposed amendment to Operating License No. NPF-18 would add requirements in the La Salle, Unit 2 Technical Specifications for new suppression pool level and water temperature instruments for the remote shutdown monitoring instrumentation to be added to Unit 2. This will fulfill License Condition 2.C.(15)(j) for La Salle Unit 2.

Basis for proposed no significant hazards consideration determination: The Commission has provided guidance concerning the application of the standards for determining whether license amendments involve no significant hazards considerations by providing certain examples (48 FR 14871). One of these examples (ii) of an amendment not likely to involve significant hazards considerations is a change that constitutes an additional limitation, restriction, or control not presently included in the Technical Specifications. The proposed amendment is directly related to this example in that new suppression pool level and water temperature instruments will be added to the remote shutdown monitoring instrumentation at the first refueling outage for Unit 2. These instruments will constitute an additional control not presently included in the remote shutdown panel. On this basis, the Commission proposes to determine that the amendment involves no significant hazards consideration.

Local Public Document Room location: Public Library of Illinois Valley Community College, Rural Route No. 1, Ogelsby, Illinois 61348.

Attorney for licensee: Isham, Lincoln and Burke, Suite 840, 1120 Connecticut Avenue, NW., Washington, DC 20036. NRC Project Director: Elinor G. Adensam.

Consumers Power Company, Docket No. 50-255, Palisades Plant, Van Buren County, Michigan

Date of amendment request: March 25. 1986 supersedes the submittal of April 10, 1984 (49 FR 21828, May 23, 1984).

Description of amendment request: The proposed amendment would change the Technical Specifications (TS) to add a limiting condition for operation for new 480 volt distribution buses that provide class 1E power for the new HVAC system and future class 1E loads, and to reflect the redistribution of certain motor control centers to the new

480 volt buses to reduce the electrical loads on existing buses.

In addition, TS 3.7.2 would be revised to reflect a revision to the Limiting Condition Operation (LCO) statement such that it will apply above primary coolant temperature of 325 °F rather than criticality, and the addition of two new LCO's to address the fuel oil storage tank level and the fuel oil transfer pumps. Also included in this change request are several editorial changes and corrections to TS 3.7 and its Bases.

Basis for proposed no significant hazards consideration determination: The first two proposed changes supersede previously proposed changes submitted in an application for amendment dated April 10, 1984. The proposed changes address the addition of 480V distribution buses 19 and 20 and the corresponding redistribution of motor control centers (MCC's) to reduce loads on other buses. The equipment was physically installed and operational for start-up following the 1983/1984 refueling outage.

The Commission has provided guidance concerning the application of standards for a no significant hazards consideration determination by providing certain examples (March 8. 1986, 51 FR 7751). One of the examples (i) of action likely to involve no significant hazards consideration relates to a purely administrative change to technical specifications. The first two proposed changes in the application for amendment are encompassed by this example since the requested action would add the new distribution buses and MCC's to the TS as well as correcting several editorial deficiencies. This administrative change to the TS would maintain consistency with the existing TS and would not involve an increase in the probability or consequences of an accident nor create a new or different kind of accident. Furthermore, no margin of safety would be affected by this proposed change. The NRC staff, therefore, proposes to determine that the requested action would involve no significant hazards consideration.

The third proposed change provides needed alignment between TS 3.7.1 and 3.7.2. TS 3.7.1 currently requires various electrical components to be operable prior to the Primary Coolant System (PCS) exceeding 325 °F. TS 3.7.2 allows the requirements of 3.7.1 to be modified to the extent that one of the listed conditions in TS 3.7.2 may be allowed after the reactor has been made critical. Thus, the PCS condition between 325 °F and critical is not addressed. The change would revise TS 3.7.2 such that

with the Primary Coolant System at a temperature greater than 325 °F, the requirements of TS 3.7.1 may be modified to permit one exception to exist. The NRC staff has evaluated this proposed change against the standards in 10 CFR 50.92 and proposes to determine that the requested action involves no significant hazards considerations, in that operation of the facility in accordance with this proposed amendment would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated . . .

The proposal would revise the LCO statement such that it would apply above PCS temperatures of 325 °F. With PCS temperatures in this range, the plant is in a subcritical condition. When subcritical, the plant is in a safer condition than when above critical. Therefore, it follows that the latitude currently afforded through the specified LCO requirement of TS 3.7.2 when the reactor is above critical should also apply above 325 °F. It also follows that at a safer condition, the probability or consequences of previously evaluated accidents would not be significantly increased.

(2) Create the possibility of a new or different type of accident from any accident previously evaluated . .

Changing the PCS temperature to above 325 °F versus when the reactor has been made critical in the LCO statement in TS 3.7.2 would not change the specifications of TS 3.7.1 or the limiting conditions for operation listed in TS 3.7.2; rather it would provide specific guidance while the plant is between 325 °F and critical and would be consistent with CE Standard Technical Specifications. Additionally, no physical modifications are required to be made to the plant in conjunction with this proposed change; therefore the proposed change will not create the possibility of a new or different type of accident from any accident previously

(3) Involve a significant reduction in a margin of safety . . .

For PCS conditions between 325 °F and critical, a literal interpretation of current Technical Specifications would require TS 3.0.3 to be invoked if any one of the requirements of TS 3.7.1 was not met. When below critical, the plant is in a safer condition than when critical; however, when critical or above, TS 3.7.2 allows more latitude through the specified LCO requirement. Thus, specifying 325 °F for both TS 3.7.1 and TS 3.7.2 would add consistency between the specifications and would not involve a significant reduction in a margin of safety.

The fourth change proposes to add two additional LCO requirements.

The first requirement would provide an LCO of 72 hours when the contents of the fuel oil storage tank fall within the limits of 16,000 gallons and 10,000 gallons. The NRC staff has evaluated this proposed change against the standards in 10 CFR 50.92 and proposes to determine that the requested action involves no significant hazards considerations in that operation of the facility in accordance with the proposed amendment would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated . . .

Existing Technical Specifications do not address the condition of less than 16,000 gallons of fuel in the storage tank, thus requiring Technical Specification 3.0.3 to be entered. However, even under the worst case loading, a sufficient amount of fuel oil is still available with only 10,000 gallons in the storage tank and 2,500 gallons (minimum volume) in the day tank for more than 4 days of diesel generator operation. It is considered incredible not to be able to secure fuel oil from one of several sources within a radius of 70 miles in less than 3 days under the worst of weather conditions; therefore, the proposed change would not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Create the possibility of a new or different type of accident from any accident previously evaluated . . .

The proposed change would not change system design; therefore, the addition of the LCO requirement would not create the possibility of a new or different type of accident from any accident previously evaluated.

(3) Involve a significant reduction in a margin of safety . . .

While the proposed LCO of 72 hours would provide operator flexibility it would not involve a significant reduction in a margin of safety for the same reasons stated above.

The second LCO requirement would provide an LCO of 16 hours in the event neither fuel oil transfer pump is operable, along with a new requirement that at least one pump be operable prior to exceeding 325 °F. The NRC staff has evaluated this proposed change against the standards in 10 CFR 50.92 and proposes to determine that the requested action involves no significant hazards considerations, in that operation of the facility in accordance with the proposed amendment would not:

(1) Involve a significant increase in the probability of consequences of an accident previously evaluated . . .

Fuel oil day tank capacity is sufficient for at least 20 hours of diesel generator operation before additional fuel would have to be transferred from the underground storage tank. Therefore, 16 hours for the fuel oil transfer pump LCO would not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Create the possibility of a new or different type of accident from any accident previously evaluated . . .

The proposed LCO does not involve a change in system design or plant equipment, and therefore would not create the possibility of a new or different type of accident from any accident previously evaluated.

(3) Involve a significant reduction in a

margin of safety

Existing Technical Specifications do not address the operability requirements of the fuel oil transfer pumps other than through a monthly surveillance requirement in section 4.7.1(e). The 16hour LCO would provide needed guidance to the operators regarding pump operability. As stated before, since over 20 hours of run time are available with the minimum day tank level, 16 hours for the fuel oil transfer pump LCO would not involve a significant reduction in a margin of safety. Furthermore, because existing TS's do not fully address the operability requirements of the fuel oil transfer pumps, this proposed change is similar to example (ii) of 51 FR 7751, in that it constitutes an additional limitation, restriction, or control not presently included in the TS's.

The last proposed change would provide editorial clarifications and corrections to TS 3.7 and its Bases. The proposed changes to the Bases section would more accurately reflect the specified minimum conditions of TS 3.7.1 with respect to fuel oil capacities and corresponding diesel generator run times. The proposed changes are similar to example (i) of 51 FR 7751 in that it relates to administrative changes to the Technical Specifications. Therefore, the NRC staff proposes to determine that the requested action would involve no significant hazards consideration.

Local Public Document Room location: Van Zoeren Library, Hope College, Holland, Michigan 49423.

Attorney for licensee: Judd L. Bacon, Esquire, Consumers Power Company, 212 West Michigan Avenue, Jackson, Michigan 49201.

NRC Project Director: Ashok C. Thadani. Consumers Power Company, Docket No. 50–255, Palisades Plant, Van Buren County, Michigan

Date of amendment request: June 20, 1986.

Description of amendment request:
The proposed amendment would
increase the allowable quantity of Cs137 contained in sealed calibration
sources used in support of operation of
the facility and add a Technical
Specification requiring leakage testing of
all sealed sources.

Basis for proposed no significant hazards consideration determination:
The licensee has reviewed the proposed change in accordance with 10 CFR 50.92 and has concluded that it does not involve a significant hazards consideration. The licensee's analysis is as follows:

- 1. The requested changes do not result in an increase in the probability or consequences of a previously evaluated accident. The change affects the allowable quantity of Cesium-137 as sealed source material. The change also provides additional administrative requirements for the control of sealed sources. The types of occurrences that would result from sealed sources are not evaluated in the FSAR. Formal evaluation of these potential occurrences is not required to assure nuclear safety, and does not relate to nuclear safety or previously evaluated accidents.
- 2. The change does not create the possibility of a new or different kind of accident. The operating license previously authorized the possession of sealed sources. Potential occurrences from these sources were not required to be formally analyzed. An analysis remains unnecessary for this category of occurrence.

The administrative requirements provided by this proposal result in additional controls not presently included in the Technical Specifications. As such, these controls will enhance the radiation safety program and the control of sealed sources. Also, these requirements are not new in that the leak testing of sealed sources is an existing program. This request only results in further emphasis on the importance of this program.

3. The change does not result in a reduction in the margin of safety. The increased possession limit affects an aspect of plant operation that is unrelated to nuclear safety. The provisions for formalized leak testing requirements in conjunction with existing procedural controls are

adequate to ensure no reduction in any type of radiological safety margin.

The staff has reviewed the licensee's no significant hazards consideration determination and agrees with the

licensee's analysis.

This change is administrative only and does not affect any accident previously analyzed in the Final Safety Analysis Report (FSAR) nor create the possibility of a new or different kind of accident and does not reduce any margin of safety. The routine health physics program maintained at the site for control and protection of radiation sources effectively covers the use and handling of these sources. Therefore, the staff proposes to determine that this change involves no significant hazards consideration.

Local Public Document Room location: Van Zoeren Library, Hope College, Holland, Michigan 49423.

Attorney for licensee: Judd L. Bacon, Esquire, Consumers Power Company, 212 West Michigan Avenue, Jackson, Michigan 49201.

NRC Project Director: Ashok C. Thadani.

Duke Power Company, Docket Nos. 50– 369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of amendment request: August 30, 1985, and supplemented December 13, 1985.

Description of amendment request: The proposed amendments would revise the surveillance requirements of Technical Specification (TS) 4.3.4.2 by deleting the existing requirements for demonstrating the Turbine Overspeed Protection System to be operable, and substituting a requirement that operability of this system be assured by inservice inspection of the various system components carried out in accordance with a "Turbine Overspeed Reliability Assurance Program' (TORAP). Associated TS Bases 3/4.3.4 "Turbine Overspeed Protection" would also be revised to reflect implementation of TORAP.

Basis for proposed no significant hazards consideration determination: In September of 1982, Westinghouse published a study on reduced testing of turbine valves based upon the Farley Nuclear Station. The study concluded that turbine valve operability and reliability is not significantly affected by lengthening the valve testing interval. The study also concluded that good operating experience, well-planned maintenance, calibration, testing and inspection programs provided reasonable bases to decrease turbine valve testing at Farley. As a result of

this study. Westinghouse has formally recommended a monthly turbine valve testing interval to utilities having similar turbines, including those at McGuire Units 1 and 2. The proposed changes to the McGuire TS arise as a result of the licensee's implementation of the Westinghouse recommendations related to periodic turbine valve testing and maintenance procedures. This proposed change to the TS would also be reflected in the bases, TS section 3/4 3.4 (Turbine Overspeed Protection) to state that TORAP is an acceptable, inclusive program for testing of the turbine valves and that tests and inspections associated with this program be in accordance with the proper station procedures.

The McGuire TORAP is a comprehensive program for periodic testing, calibration, maintenance and inspection of the Turbine Overspeed Protection System. The overall intent of this program is to maintain the reliability and operability of the Turbine Overspeed Protection System and to minimize the potential for turbine missile generation. The program is described as follows:

(A) The McGuire testing program addresses the turbine valves and the turbine overspeed protection controls. The testing program is performed during each turbine startup, unless tested within the previous 7 days, including startup after each refueling outage. This program also includes a test of all the turbine valves on a 4 months interval;

(B) Calibration of the electrical and mechanical overspeed trip devices is performed during each refueling outage or following major maintenance on the turbine or the overspeed protection

control systems; and,

(C) The turbine valve maintenance program includes inspection and maintenance of all throttle, governor, reheat stop and intercept valves every 40 months. This work consists of removing valve internals and cleaning, inspecting, and repairing valve

components.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations (10 CFR 50.92) this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The bases for this proposed determination are as follows:

The licensee has determined that the major components of the Turbine and **Electronic Overspeed Protection** Systems are identical at McGuire and Farley. Preliminary review by the Commission supports this conclusion by the licensee. Because our review of the Farley study concluded that the turbine valve testing interval could be increased without significantly increasing the probability of turbine missile generation, and because of the identical designs of the McGuire and Farley Protection Systems, this proposed change to McGuire would not involve a significant increase in the probability or consequences of an accident previously evaluated. These changes would not (2) create the possibility of a new or different kind of accident from any accident previously evaluated because the changes are limited to surveillance requirements and would not change any hardware or operating procedures, and from its preliminary review, the Commission finds that TORAP meets the intent of the existing surveillance requirements in TS 3/4.3.4. Similarly, these changes would not (3) involve a significant reduction in a margin of safety because the Commission's preliminary review supports the licensee's conclusion that the TORAP will maintain the reliability and operability of the Turbine Overspeed Protection System and will minimize the potential for turbine missile generation. Accordingly, the staff proposes to determine that this request does not involve a significant hazards consideration.

Local Public Document Room location: Atkins Library, University of North Carolina, Charlotte (UNCC Station), North Carolina 28223.

Attorney for licensee: Mr. Albert Carr, Duke Power Company, 422 South Church Street, Charlotte, North Carolina 28242.

NRC Project Director: B.J. Youngblood.

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket No. 50–321; Edwin I. Hatch Nuclear Plant, Unit No. 1, Appling County Georgia

Date of amendment request: April 15, 1986.

Description of amendment request:
These amendments would modify the
Technical Specifications (TS) to: (1)
Correct Table 3.7–1 to (a) reflect the
current plant design and include all
automatic primary containment isolation
valves (PCIVs) that receive a primary
containment isolation signal and are

subject to surveillance as specified in TS section 4.7.D.I, and (b) delete the valves that do not receive a primary containment isolation signal (check valves); (2) Change the title of Table 3.7–1; (3) Delete the reference in section 3.7.D.1 to Table 3.7–1 such that section 3.7.D.1 will state that all PCIVs shall be operable instead of only those PCIVs listed in Table 3.7–1; and (4) Correct Table 3.7–4 to reflect changes in the plant design, to include all PCIVs and to delete those valves that are not PCIVs.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The changes expand and correct the listing of valves in Tables 3.7-1 and 3.7-2. They will better assure that all the valves that are required to be tested for operability and leak tightness are identified and tested. This should insure the margin of safety provided by the isolation system. These changes are not expected to (1) increase the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident previously evaluated.

On the basis of the above, the Commission has determined that the requested amendments meet the three criteria and therefore has made a proposed determination that the amendment application does not involve a significant hazards consideration.

Local Public Document Room location: Appling County Public Library, 301 City Hall Drive, Baxley, Georgia.

Attorney for licensee: Bruce W.
Churchill, Esquire, Shaw, Pittman, Potts
& Trowbridge, 1800 M Street, NW.,
Washington, DC 20036.

NRC Project Director: Daniel R. Muller.

GPU Nuclear Corporation, et al., Docket No. 50–289, Three Mile Island Nuclear Station, Unit No. 1, Dauphin County, Pennsylvania

Date of amendment request: June 26, 1986.

Description of amendment request: The current Technical Specifications (TSs) for TMI-1 state that there are four smoke detectors in the Auxiliary Building at elevation 281 feet in the cable gallery area (Fire Zone 4). However the TSs only require two of the four smoke detectors to be operable. This minimum number of required operable smoke detectors in this fire zone is consistent with the TMI-1 Fire Hazards Analysis.

One of the four detectors (labeled AB-4-3) is in an inaccessible location and must generally be considered inoperable due to a lack of normal maintenance. By this application, the licensee seeks to remove this single fire detector from the TSs. The minimum number of required operable smoke detectors in Fire Zone 4

remains unchanged.

Basis for proposed no significant hazards consideration determination: The Commission's staff has reviewed the licensee's no significant hazards consideration finding and agrees with the licensee's discussion of the three factors involved. In 10 CFR 50.92, the Commission provided three standards to be considered in making a no significant hazards consideration finding. Each standard is discussed in turn:

(1) The proposed amendment should not involve a significant increase in the probability or consequences of an accident previously evaluated. The design basis accident related to this change is a fire in Auxiliary Building Elevation 281'-0" Cable Gallery Zone 4. Deletion of one smoke detector (AB-4-3) has no effect on the probability of occurrence of a fire in this zone. Also, the consequences of a fire in this zone are not affected because the minimum number of fire detectors required to be operable in this zone, in accordance with existing TSs, has not been reduced.

(2) The proposed amendment should not create the possibility of a new or different kind of accident from any accident previously evaluated. The detector being deleted must be considered inoperable for long periods of time because it is in an inaccessible location for normal maintenance. The deletion of a detector which is not required for adequate detection capability does not create a new or different kind of design basis accident from that previously evaluated in the Fire Hazards Analysis.

(3) The proposed amendment should not involve a significant reduction in a margin of safety. The minimum number of smoke detectors required to be operable in this fire zone is not changed by this amendment. Thus the margin of safety provided by the remaining smoke detectors located in the affected fire zone has not been reduced.

Based on the three factors discussed above, the Commission makes a proposed determination that the amendment request involves no significant hazards considerations.

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania, Education Building, Commonwealth and Walnut Streets, Harrisburg, Pennsylvania 17126.

Attorney for licensee: G.F.
Trowbridge, Shaw, Pittman, Potts and
Trowbridge, 1800 M Street, NW.,
Washington, DC 20036.

NRC Branch Chief: John F. Stolz.

GPU Nuclear Corporation, et al., Docket No. 50–289, Three Mile Island Nuclear Station, Unit No. 1, Dauphin County, Pennsylvania

Date of amendment request: July 16, 1986.

Description of amendment request: The current TMI-1 Technical Specifications (TSs) allow operation for 250 ±10 effective full power days (EFPD) during the present cycle (i.e. Cyle 5) of operation. By this application, the licensee is requesting an extension of the Cycle 5 length to 290 ±15 EFPD. This is accomplished by allowing the withdrawal of axial power shaping rods (APSRs) under end-of-cycle (EOC) core conditions. If approved, the overall result of this application would allow continued plant operation until about November 1, 1986, before beginning the Cycle 6 refueling outage.

Basis for proposed no significant hazards consideration determination: The withdrawal of the APSRs near the end of the cycle has become a routine operational procedure at several plants designed by Babcock & Wilcox (B&W). The conclusions in the licensee's analysis are consistent with results obtained on similar plants.

The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92. A proposed amendment to an operating license for a facility involves no significant hazards consideration if it meets three standards as described in 10 CFR 50.92. Each standard is discussed in turn.

Standard 1—The proposed amendment should not involve a significant increase in the probability or consequences of an accident previously evaluated. The licensee's analysis concludes that the APSR withdrawal and subsequent longer cycle length introduce small changes to the EOC physics parameters. The licensee reviewed the Final Safety Analysis Report (FSAR) events relative to the

EOC core physics parameter changes at EOC due to APSR withdrawal. The results of this review confirm that the events analyzed in Chapter 14, "Safety Analysis," of the TMI-1 FSAR and the TMI-1 Cycle 5 Reload Report remain bounding for Cycle 5 operation. On this basis, the Commission has determined that the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Standard 2-The proposed amendment should not create the possibility of a new or different kind of accident from any accident previously evaluated. Analysis conducted by B&W for the licensee using approved methods concludes that the APSR withdrawal is conservatively bounded by the existing safety analysis in all cases. In particular, the events directly affected by EOC physics parameters are overcooling transients (such as a steam line failure or cold water accident) and a dropped control rod. In each case reviewed, the licensee's analysis concludes that the existing safety analysis conservatively bounds potential accidents with the APSRs removed. It is thus determined that the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Standard 3—The proposed amendment should not involve a significant reduction in a margin of safety. The licensee's analysis concludes that the existing safety analysis conservatively bounds potential accidents with the APSRs removed. All safety criteria as described in the TS bases are preserved by the revised limits. It is therefore determined that the proposed amendment does not involve a significant reduction in a margin of safety.

Accordingly, based on the above discussions, the Commission proposes to determine that the proposed amendment does not involve significant hazards considerations.

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania, Education Building, Commonwealth and Walnut Streets, Harrisburg, Pennsylvania 17126.

Attorney for licensee: G.F. Trowbridge, Shaw, Pittman, Potts and Trowbridge, 1800 M Street, NW., Washington, DC 20036.

NRC Project Director: John F. Stolz.

Kansas Gas & Electric Company, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas.

Date of amendment request: March 4, 1986.

Description of amendment request:
This amendment requests revision of
Wolf Creek Generating Station,
Technical Specification Figure 6.2-1,
Figure 6.2-2, and section 6.5.2.2 to reflect
a title change, a change in reporting
relationship, the correction of
typographical errors, addition and
deletions of groups from the Unit
Organization chart the addition of
positions and groups to the Nuclear
Department organization, and two
changes in membership to the Nuclear
Safety Review Committee.

Basis for proposed no significant hazards consideration determination: The first requested revision changes the title "Procurement & Materials Superintendent," Figure 6.2–1, to "Procurement & Materials Manager". This is an administrative change that does not constitute a change in reporting relationships or overall organizational commitments.

The second revision changes the reporting relationship of onsite Emergency Planning, Figure 6.2–2, from the Supt. of Regulatory, Quality and Administrative Services to the Supt. of Plant Support. This change represents an organizational enhancement by altering reporting relationships. This does not constitute a change in job responsibilities, or overall organizational commitments.

The next three changes rectify clerical errors present in the Wolf Creek Generating Station Technical Specifications. The titles "Manager Operations Support," Figure 6.2–1, and "Ops Coordinator Planning and Projects," Figure 6.2–2, are being corrected to read "Manager Nuclear Operations Support" and "Ops Coordinator Projects and Planning" respectively. In addition, the spelling of "Security," Figure 6.2–2, is also being corrected.

The next four changes are being made to Figure 6.2–2 in order to reflect a more accurate and consistent organizational representation. The Safety and Medical groups, reporting to the Supt. of Plant Support and the Supt. of Regulatory, Quality and Administrative Services respectively, are existing groups being added for completeness. The Computers group, reporting through the Instrument & Controls group to the Supt. of Technical Support, is being deleted in order to reflect a consistent level of organizational detail. The Utility Helper position, reporting through Ops Coord-

Ops to the Supt. of Operations, is being deleted since this position no longer exists. Its function is fulfilled by personnel in other existing positions. These changes do not constitute a change in reporting relationships or overall organizational commitments.

The final three requested revisions to Figures 6.2-1 and 6.2-2 reflect positions and groups that have been added to the Nuclear Department organization. These revisions represent organizational enhancements and augmentations that do not effect any existing reporting relationships or overall organizational commitments. In Figure 6.2-2 a Compliance group is being added to the Unit Organization. This group reports to the Supt. of Regulatory, Quality and Administrative Services. The positions Supervisor Project Plans & Schedule, reporting to the Director Nuclear Operations, and the position Manager Engineering & Technical Services Support reporting to the Director Engineering and Technical Services, have been added to the Offsite Organization shown in Figure 6.2-1.

Section 6.5.2.2 is being revised changing the Nuclear Safety Review Committee (NSRC) membership list to reflect a Nuclear Department organizational change, which deleted the position Manager Licensing and Radiological Services, and the recent retirement of the Vice President Engineering. The NSRC membership list is being revised to read "Manager Licensing" rather than "Manager Licensing and Radiological Services." The Manager Radiological Services and Manager Licensing report directly to the Manager Nuclear Services, who is the NSRC Chairman. Thus the Manager Nuclear Services can fully address issues involving Radiological Services, while the Manager Licensing is present as a committee member to address licensing issues. Additionally, the NSRC membership list is being revised to read "KCP&L Senior Director of Nuclear Affairs" rather than "Vice President-Engineering." Kansas Gas and Electric Company's Vice President—Engineering recently retired. His position on the NSRC is being filled by Kansas City Power & Light Company's Senior Director of Nuclear Affairs who has extensive experience in nuclear industry. Therefore, the requested revision does not affect the level of expertise present in the NSRC since the same technical and management responsibilities are still represented.

The Commission has provided guidance concerning the application of the standards in 10 CFR 50.92 by providing examples of Amendments that are not likely to involve Significant Hazards Considerations (51 FR 7744). Among those examples are, (i) "A purely administrative change to technical specifications: for example, a change to achieve consistency throughout the Technical Specifications, corrections of an error, or a change in nomenclature' and (ii) "A change that constitutes an additional limitation, restriction, or control not presently included in the technical specifications . . .'

The above requested revisions to the Wolf Creek Generating Station, Unit No. 1, Technical Specification Figure 6.2-1, Figure 6.2-2, and Section 6.5.2.2 are similar to the above cited examples that are not likely to involve significant hazards considerations and do not involve a significant increase in the probability or consequences of an accident or other adverse condition over previous evaluations; or create the possibility of a new or different kind of accident or condition over previous evaluations; or involve a significant reduction in a margin of safety. Based on this information and utilizing the guidance provided by the Commission, the requested license amendment does not present a significant hazard.

Local Public Document Room location: The William Allen White Library, Emporia State University, Emporia, Kansas; and the Washburn University School of Law, Topeka,

Kansas. Attorney for licensee: Jay Silburg, Esquire, Shaw, Pittman, Potts, & Trowbridge, 1800 M Street, NW., Washington, DC, 20036. NRC Project Director: B.I.

Youngblood.

Pacific Gas and Electric Company, Docket Nos. 50-275 and 50-323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: June 10, 1986 (LAR 86-06).

Brief description of amendments: The proposed amendment would revise the Diablo Canyon combined Technical Specifications (TS) for Units 1 and 2 to accommodate Cycle 2 operation of Unit 1. The proposed TS changes would (1) allow operation with a small positive moderator temperature coefficient (MTC), (2) allow optimization of core loading patterns by minimizing the restriction of FN-delta-H at low power, and (3) remove the description for the uranium weight in a fuel rod. The specific changes would include the following:

 Technical Specification 3/4.1.1.3. Moderator Temperature Coefficient, and related Bases. The specification would

be changed to allow a maximum positive MTC of $+5 \times 10^{-5}$ delta-k/k/°F at power levels below 70%, with the maximum positive MTC decreasing linearly to 0 delta-k/k/°F between 70% and 100% power during beginning of life (BOL) operation. In addition, TS Bases 3/4.1.1.3 would be supplemented to clarify the requirement that MTC parameters are verified to be within the limits during startup testing at BOL hot zero power for each cycle. The present Technical Specifications require the MTC to be zero or negative at all times while the reactor is critical. To assess the effects of a slightly positive MTC, a safety evaluation of transients sensitive to a positive MTC was performed by Westinghouse for Pacific Gas and Electric Company. Evaluation results demonstrate that a small positive MTC does not affect the LOCA analysis and has only a minor effect on other safety analyses results provided in the Diablo

Canyon FSAR Update.

(2) Technical Specification 3/4.2.3, RCS Flow Rate and Nuclear Enthalpy Rise Hot Channel Factor, and Safety Limit 2.1.1, Reactor Core, including related Bases 2.1.1. The FN-delta-H partial power multiplier in Technical Specification 3.2.3 and associated Figure 3.2-3a would be changed from 0.2 to 0.3 for Unit 1 only. No change would be made in the FN-delta-H limit at full power. The increased FN-delta-H partial power multiplier also affects the calculation of departure from nucleate boiling ratio (DNBR). Reevaluation of the safety limits for the reactor core showed that a revision to the Safety Limit curve (TS Figure 2.1-1) was required. Therefore, the present Figure 2.1-1 would be redesignated Figure 2.1-1b for applicability to Unit 2 only and a new Figure 2.1-la for Unit 1 would be added to the Technical Specifications. Safety Limit 2.1.1 and Bases 2.1.1 would be revised to reflect the figure number changes and Bases 2.1.1 would be further revised to reflect the Unit 1 FNdelta-H change. The proposed revision would allow optimization of core loading patterns by minimizing the restriction of FN-delta-H at low power levels. Also, the revision would minimize the need to make control rod insertion limit changes in future reload cycles to satisfy peaking factor criteria at low power. A safety evaluation for the revised F^N-delta-H partial power multiplier was performed by Westinghouse for Pacific Gas and Electric Company. The results show that the LOCA analysis and other accident analyses in the FSAR Update are not affected by the proposed changes.

(3) Design Feature TS section 5.3.1, Fuel Assemblies. The proposed changes

would delete the description related to the maximum weight of the uranium contained in each fuel rod. The purpose of deleting the fuel rod uranium weight in an assembly would be to permit the use of as-manufactured fuel assemblies containing fuel rods in which the uranium weight slightly exceeds 1766 grams due to recent improvements in fuel design, including the use of chamfered pellets with a reduced dish and an increase in as-built density. Inclusion of the fuel rod uranium weight limit in the Technical Specifications was intended to be descriptive and representative of fuel used in the reactor. The uranium weight is not used as a direct input to any safety analysis; therefore, deletion of the weight limit is not significant to safe operation of the plant.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has determined that the

proposed revision will not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated because (a) transients sensitive to a positive MTC have been reanalyzed and show that operation with the proposed positive MTC has an insignificant effect on analysis results; (b) evaluation of the accident analyses contained in the FSAR Update shows that the proposed increase in FN-delta-H does not impact the analyses and, therefore, no reanalysis is necessary; and (c) the fuel rod uranium weight is not used as direct input to any safety analysis.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated because the proposed changes do not necessitate physical alteration of the plant or changes to operating procedures.

(3) Involve a significant reduction in the margin of safety because (a) reanalysis of accidents with the proposed positive MTC has shown no significant increases in consequences; (b) the proposed increase in FN-delta-H does not affect the accident analyses; and (c) constraints on fuel design and operating parameters other than uranium weight ensure the margin of safety is maintained.

Accordingly, the licensee has determined that the proposed changes to the Technical Specifications involve no significant hazards consideration.

The NRC staff has reviewed the proposed amendments and the licensee's determination and finds them acceptable. Therefore, the staff proposes to determine that a no significant hazards consideration is involved in the proposed amendments.

Local Public Document Room location: California Polytechnic State University Library, Government Documents and Maps Department, San Luis Obispo, California 93407.

Attorneys for Licensee: Philip A. Crane, Esq., Richard F. Locke, Esq., Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, California 94120 and Bruce Norton, Esq., Norton, Burke, Berry and Perkins, P.O. Box 10569, Phoenix, Arizona 95064.

NRC Project Director: Steven A. Varga.

Portland General Electric Company, et al., Docket No. 50–344, Trojan Nuclear Plant, Columbia County, Oregon

Date of amendment request: January 31, 1986.

Description of amendment request: The amendment proposes changes to the Trojan Technical Specifications (TTS) as follows:

(1) TTS 4.0.2.b (surveillance intervals) is revised to correct a typographical

(2) TTS 4.4.6.1.b (surveillance of leakage detection systems) is revised to correct an editorial error.

"CALIBRATION TEST" is changed to "CHANNEL CALIBRATION."

"CALIBRATION TEST" is not a defined term in TTS 1.0, whereas "CHANNEL CALIBRATION" is defined and correctly describes the surveillance performed.

(3) TTS 3.4.9.3. (Overpressure Protection System) is revised to correct an editorial error. The correct Reactor Coolant System vent size is 3.40 square inches, not 3 square inches.

(4) TTS Table 3.6–1 (Containment Isolation Valves) is revised to delete valve CV–8825. This valve is the RHR hot leg recirculation valve inside Containment. The basis for not including this valve is that this piping penetration is Type IV. Type IV penetrations are required for post-Design Basis Event operation. By definition, Type IV penetrations only require one barrier. This barrier is provided by valve MO–

8703 (RHR hot leg recirculation outside containment), which is still included in Table 3.6–1.

TTS Table 3.6-1 is also revised to allow manual valve MD-059 (demineralized water washdown) to be periodically opened under administrative control. This is accomplished by referencing the new footnote in Table 3.6-1 which is denoted by ##. Valve MD-059 is opened to provide water to the Containment for fire protection when activities occurring inside Containment may pose a fire hazard. The availability of water is required per TTS 3.7.8.3, "Fire Hose Stations". Administratively controlling the opening of valve MD-059 will allow TTS 3.6.1.1, 3.6.3.1 and 3.7.8.3 to be

Basis for proposed no significant hazards consideration determination: 10 CFR 50.92 states that a proposed amendment will involve a no significant hazards consideration if the proposed amendment does not: (i) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (ii) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (iii) Involve a significant reduction in a margin of safety.

Proposed Changes (1), (2) and (3): The Commission has provided guidance for the criteria for no significant hazards consideration determinations by providing examples of amendments that are considered not likely to involve a significant hazards consideration (48 FR 14870). These examples include: (1) A purely administrative change to the Technical Specifications: for example, a change to achieve consistency throughout the Technical Specifications, correction of an error, or a change in nomenclature. Since example (1) applies to proposed changes (1), (2) and (3), the staff proposes to determine that the proposed changes (1), (2), and (3) do not involve a significant hazards consideration.

Proposed Change (4):

Criterion (i)—A Significant Increase in the Probability or Consequences of an Accident Previously Evaluated

The first change to TTS Table 3.6–1 (Containment Isolation Valves) deletes a valve (valve CV–8825, RHR hot leg recirculation to SIS test line inside containment) which is associated with a Type IV piping penetration. As discussed in FSAR section 6.2.5.1, Type IV penetrations are those fluid lines which must remain in service subsequent to a Design Basis Event. Type IV penetrations are required to have one containment isolation valve.

Valve MO-8703 (RHR hot leg recirculation—outside containment) is the containment isolation valve of this piping penetration, not CV-8825. Since Valve CV-8825 is not the containment isolation valve required for the RHR hot leg recirculation penetration, it is currently inappropriately placed in Table 3.6-1. Deletion of this valve from TTS Table 3.6-1 would not increase the probability or consequences of an accident previously evaluated since the surveillance and operability requirements will still be maintained for the containment isolation valve (MO-8703).

The second change to TTS Table 3.6-1 resolves a conflict between TTS 3.6.1.1, Containment Integrity, and TTS 3.7.8.3, Fire Hose Stations. TTS 3.6.1.1 requires, via the provisions of TTS 3.6.3.1 and Table 3.6-1, that containment integrity be maintained during MODES 1, 2, 3 and 4. Valve MD-059, which is governed under TTS 3.6.3.1 is also governed by TTS 3.7.8.3, Fire Hose Station, which requires the availability of water for fire protection during the same MODES of operation when activities occuring inside containment pose a fire hazard. Since valve MD-059 would be opened to make demineralized water available for fire protection inside containment, and since TTS 3.6.1.1 requires that this valve be closed from a Containment integrity standpoint, administrative controls would be established for this valve to ensure it was closed once the work inside Containment was completed. These administrative controls include, but are not limited to, including on the valve checkoff sheet for Plant operational mode changes. Allowing valve MD-059 to be opened under administrative control will allow TTS 3.7.8.3. to be met, while also satisfying TTS 3.6.1.1 and TTS 3.6.3.1. A check valve is available inside containment to isolate containment and valve MD-059 could be immediately closed if necessary. Therefore, this change would not increase the probability or consequences of an accident previously evaluated.

Criterion (ii)—A New or Different Kind of Accident

The changes to TTS Table 3.6–1 are not related to creating a new or different kind of accident, but rather, deal with accident mitigation as related to containment integrity. As previously discussed, containment integrity is not compromised by this change and the change will not create the possibility of a new or different accident.

Criterion (iii)—A Significant Reduction in Margin of Safety

The changes to TTS Table 3.6–1 do not compromise containment integrity. Therefore, no reduction in the safety provided by the containment is proposed. From the fire protection standpoint, as related to valve MD–059, with this valve open the availability of fire water inside containment is assured and safety is enhanced. Therefore, this change will not significantly reduce a margin of safety.

Based on the above, the staff proposes to determine that proposed change (4) does not involve a significant hazards consideration. In summary, the staff proposes to determine that none of the proposed changes (1), (2), (3) and (4) involves a significant hazards

consideration.

Local Public Document Room location: Multnomah County Library, 801 S. W. 10th Avenue, Portland, Oregon.

Attorney for licensee: J.W. Durham, Senior Vice President, Portland General Electric Company, 121 SW. Salmon Street, Portland, Oregon 97204.

NRC Project Director: Steven A. Varga.

Portland General Electric Company, et al., Docket No. 50-344, Trojan Nuclear Plant, Columbia County, Oregon

Date of amendment request: June 12, 1986.

Description of amendment request: The application for amendment requests modifications to the Trojan Technical Specification (TTS) contained in Appendix A to Operating License No. NPF-1. Specifically, TTS 4.7.5.1, Ultimate Heat Sink Surveillance Requirements, would be modified to define the Cooling Tower basin as the portion of the ultimate heat sink which shall be determined operable by surveillance. Additionally, the Bases of TTS 3/4.5.7 would be modified to define the Columbia River as the ultimate heat sink with the Cooling Tower as the backup. These changes would make the TTS consistent with the FSAR and does not involve any changes to procedures, equipment, or surveillance.

Basis for proposed no significant hazards consideration determination: 10 CFR 50.92 states that a proposed amendment will not involve a significant hazards consideration if the proposed amendment does not: (i) Involve a significant increase in the probability of consequences of an accident previously evaluated; or (ii) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (iii) Involve a significant reduction in

a margin of safety. Accordingly, the licensee has performed the following analysis:

(i) Does the proposed license amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

While the title of Trojan Technical Specification section 3/4.7.5 is Ultimate Heat Sink, subsection 3.7.5.1 states the Limiting Condition for Operation of the Cooling Tower basin. The inspection requirement of Section 3.7.5.1, Surveillance Requirement 4.7.5.1, thus, has always applied directly to the Cooling Tower basin and not the ultimate heat sink, the Columbia River, as the current wording of the section title implies. Throughout the previous 10 years of commercially operating Trojan, the staff has verified the Limiting Condition for Operation of the Cooling Tower basin by inspecting the operability of the Cooling Tower basin. By stating that the direct subject of Surveillance Requirement 4.7.5.1, the Cooling Tower basin, will be inspected and not the ultimate heat sink, the Columbia River, neither the probability or consequences of an accident are increased.

(ii) Does the proposed license amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

The Columbia River has always been the ultimate heat sink. Inspection to satisfy Surveillance Requirement 4.7.5.1 have always been performed on the Cooling Tower basin. The changes requested in this LCA, to both the surveillance requirement and the Bases, have been shown in the response of Question (i) not to make any change to use or surveillance of equipment and, thus, does not create the possibility of a new or different kind of accident from any accident previously evaluated.

(iii) Does the proposed amendment involve a significant reduction in a

margin of safety?

The margin of safety (100 hours of cooling water supply to safety-related equipment) provided by the Cooling Tower basin (the subject of TTS 3/4.7.5.1 and the Bases) will not be affected by replacing the misleading words ultimate heat sink by the actual equipment title, the Cooling Tower Basin, in TTS 4.7.5.1 nor by the editorial changes made to the Bases editorial, see Paragraph 1 of the response to Question 1.

In the April 6, 1983 Federal Register, the NRC published a list of examples of amendments that are not likely to involve a significant hazards concern. Example No. 1 of that list applies to the clarification of the Ultimate Heat Sink Surveillance Requirement and Bases.

Example No. 1 states: "A purely administrative change to the technical specifications: for example, a change to achieve consistency throughout the technical specifications, correction of an error, or a change in nomenclature."

Based on the above analysis, the licensee concluded that the proposed amendment does not involve a significant hazards consideration. The staff has reviewed the licensee's no significant hazards consideration and agrees with the licensee's analysis. The staff has, therefore, made the initial determination that the licensee's request does not involve a significant hazards consideration.

Local Public Document Room location: Multnomah County Library, 801 S.W. 10th Avenue, Portland, Oregon.

Attorney for licensee: J.W. Durham, Senior Vice President, Portland General Electric Company, 121 SW. Salmon Street, Portland, Oregon 97204.

NRC Project Director: Steven A. Varga.

Public Service Company of Colorado (PSC/, Docket No. 50-267, Fort St. Vrain Nuclear Generating Station, Platteville, Colorado

Date of amendment request: June 4, 1986.

Description of amendment request: This proposed amendment updates an earlier amendment request made on December 31, 1985 and noticed in the Federal Register on March 12, 1986 at 51 FR 8600. The proposed amendment incorporates the requirements for the licensee's Steam Line Rupture Detection/Isolation System (SLRDIS) at the Fort St. Vrain Nuclear Generating Station. Specifically, this proposed amendment adds new limiting conditions for operation and surveillance requirements to assure that the SLRDIS will perform its design function should the reactor require this protective function. Requirements for the existing Steam Pipe Rupture Detection System will be deleted.

Basis for proposed no significant hazards consideration determination:
Based upon PSC Safety Analysis Report (EE-EQ-0014), Steam Line Rupture
Detection/Isolation System (SLRDIS), it is concluded that the SLRDIS is capable of performing its intended function to detect and isolate major ruptures of high energy steam lines of the secondary cooling system without operator intervention. The resulting harsh environments from a SLRDIS-terminated leak are less severe than the harsh environments previously established on

the basis of the operator manually terminating the leak at 4 minutes. These operator-terminated leaks previously established the harsh environments used for Fort St. Vrain equipment

qualification.

The SLRDIS replaces the existing steam pipe rupture detection system. The SLRDIS is designed to detect steam leaks in either the reactor or turbine buildings and isolate those leaks to preserve or maintain an environment in which electrical equipment is qualified. This change in steam leak detection and automatic action provides more inclusive coverage of potential steam leaks and results in no change in the radiological consequences. For certain steam leaks, the SLRDIS has a slower response than the existing system, but analysis demonstrates that equipment qualification is maintained. Thus, the existing steam pipe rupture detection system will no longer be required.

Manual operator intervention for isolation of high energy line breaks in the feedwater, condensate and extraction steam systems and those line breaks not isolated by the SLRDIS is adequate to assure that the resulting temperature profiles are enveloped by that to which the equipment will be

qualified.

Consequences of other accidents analyzed in the Final Safety Analysis Report (FSAR) were examined for adverse impact as a result of the installation of the SLRDIS. Design Basis Accident No. 2 (DBA-2), "Rapid Depressurization/Blowdown Accident", was determined to have one assumption invalidated in that the SLRDIS could prevent initiation of forced circulation cooling at 5 minutes into the accident. (This is because the escaping hot helium gas could trigger the SLRDIS, and interrupt steam drive to the operating circulators.) Reanalysis of the accident determined that forced circulation cooling could be delayed for at least 60 minutes without exceeding the conservative FSAR temperature for onset of fuel particle failure of 2900 degrees F, a temperature well below that at which rapid fuel deterioration is expected to occur. This is more than ample time for the operator to restore forced circulation cooling.

The potential for the SLRDIS to create new or different types of accidents not previously analyzed was examined. The conclusion was that a SLRDIS actuation initiated by a high energy line break, fires or primary coolant leaks may result in an interruption of forced circulation cooling. It was further concluded that sufficient information is currently available in conjunction with new information available from the SLRDIS

for the operator to properly diagnose and recover from the event by reestablishing forced circulation cooling within 60 minutes. The 60-minute forced circulation recovery is the most limiting recovery time and is associated with DBA-2. For all other accidents, 90 minutes is adequate time to restore forced circulation cooling prior to reaching 2900 degrees F. Surveillance testing or faults associated with a single panel of the SLRDIS will not cause a SLRDIS actuation.

A review was conducted to determine if any margins of safety defined in the basis for a Technical Specification or in the FSAR were significantly decreased. It was concluded that a SLRDIS isolation of the secondary coolant system only causes a temporary interruption of forced circulation cooling in both loops. A recovery methodology exists and a recovery procedure will be developed to reestablish forced circulation cooling within the most limiting time associated with the DBA-2 accident-60 minutes. Thus, it is concluded that the margin of safety is not significantly reduced.

Based on the above evaluation, it is concluded that operation of Fort St.
Vrain in accordance with the proposed changes will not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in any margin of safety. Therefore, this change does not involve any significant hazards

considerations.

Local Public Document Room location: Greeley Public Library, City Complex Building, Greeley, Colorado.

Attorney for licensee: Bryant O'Donnell, Public Service Company of Colorado, P.O. Box 840, Denver, Colorado 80201.

NRC Project Director: Herbert N. Berkow.

South Carolina Electric and Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit 1, Fairfield County, South Carolina

Date of amendment request: June 27, 1986.

Description of amendment request:
The proposed amendment would modify
Technical Specification 3.2.3, "RCS Flow
Rate and Nuclear Enthalpy Rise Hot
Channel Factor," the associated Bases,
and Figure 3.2–3 to reflect a flow
measurement uncertainty of 2.1%
instead of 3.5% as currently listed in
Technical Specifications. The proposed
change to Figure 3.2–3 would allow

continued operation at lower indicated RCS flow rates due to a reduced RCS flow measurement uncertainty of 2.1% while ensuring the thermal design flow requirement.

Basis for proposed no significant hazards consideration determination: Specification 3.2.3 in the Standard Technical Specifications requires that total reactor flow (total flow through the vessel from all loops) be above some minimum value. The minimum flow value is thermal design flow corrected for the total flow measurement uncertainties. Historically, the uncertainty has been specified as 3.5% due to uncertainties associated with feedwater venturi fouling. Flow measurement uncertainties much less than this can be achieved by using modern statistical error analyses and normalizing elbow tap flow indications with a precision calorimetric flow measurement.

The RCS flow rate measurement is required by Technical Specification 4.2.3.2 at least once every thirty-one (31) effective full power days. The elbow tap flow measurement is presently the basis for the Technical Specification total flow measurement uncertainty. Normalizing the elbow tap flow measurement with the initial precision heat balance reduces the uncertainty by eliminating errors due to the transmitters calibration, feedwater venturi fouling, and temperature and pressure effects. Thus, with a more accurate determination of RCS flow rate, the required measured flow rate can be reduced. Whenever the process computer display is unavailable, the RCS flow rate will be determined using digital voltmeter (DVM) readings from the process instrument racks.

To establish the overall flow measurement uncertainty, the accuracy and relationship to RCS flow of each instrument used for the calorimetric measurements and elbow tap flow measurement (using either the process computer or the DVM) has been determined. The overall loop flow measurement uncertainty is the statistical summation of individual uncertainties (accounting for interactive

effects where necessary).

In summary, individual loop flow is determined by performance of a precision calorimetric and these values are used to normalize elbow tap measurements. The loop flow measurements are summed to arrive at the total RCS flow. The measurement uncertainty is determined by statistically combining precision calorimetric and elbow tap flow measurement uncertainties. A precision

calorimetric flow measurement must be performed to normalize the elbow taps to take credit for this particular measurement uncertainty.

The Commission has provided certain examples (48 FR 14870) of actions likely to involve no significant hazards considerations. The request involved in this case does not match any of those examples. However, the staff has reviewed the licensee's request for the above amendment and determined that should this request be implemented, it will not (1) involve a significant increase in the probability or consequences of an accident previously evaluated because the thermal design flow is not changed, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated because the physical plant design is not being changed. Also, it will not (3) involve a significant reduction in a margin of safety because the flow measurement uncertainty is being reduced only 1.4%. Accordingly, the Commission proposes to determine that this change does not involve significant hazards considerations.

Local Public Document Room location: Fairfield County Library, Garden and Washington Streets, Winnsboro, South Carolina 29180.

Attorney for licensee: Randolph R. Mahan, South Carolina Electric and Gas Company, P.O. Box 764, Columbia, South Carolina 29218.

NRC Project Director: Lester S. Rubenstein.

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit No. 1, Callaway County, Missouri

Date of amendment request: October 16, 1985.

Description of amendment request:
The purpose of the proposed
amendment is to revise the Callaway
Plant Reactor Trip System (RTS)
Instrumentation Technical
Specifications based on the NRC Staff's
previous review and approval of
Westinghouse topical report WCAP10271 and its Supplement 1. The
proposed revisions are summarized as
follows:

 Increase the surveillance interval for RTS analog channel operational tests from once per month to once per quarter,

2. Increase the time during which an inoperable RTS analog channel may be maintained in an untripped condition from one hour to six hours, and

3. Increase the time an inoperable RTS analog channel may be bypassed to allow testing of another channel in the same function from two hours to four hours.

These changes are three of the four changes proposed by WCAP-10271 and Supplement 1 and approved as part of the NRC's Safety Evaluation Report dated February 21, 1985. A fourth change discussed in WCAP-10271 and the February 21, 1985 SER would allow testing of RTS analog channels in a bypassed condition instead of a tripped condition. The Callaway design does not currently include the capability for bypass testing. Therefore, the portion of WCAP-10271 and its Supplement 1 which concerns bypass testing is not applicable to this amendment request.

Basis for proposed no significant hazards consideration determination: The Commission has provided certain examples (51 FR 7744) of actions likely to involve no significant hazards considerations. The request involved in this case does not match any of those examples. However, the Commission has reviewed the licensee's request for the above amendments and has determined that should this request be implemented, it would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The bases for these conclusions follow:

Criterion 1—Operation of Callaway Unit 1 in accordance with the proposed license amendments would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes affect the Reactor Trip System (RTS), the system which monitors reactor system conditions and scrams the reactor when those conditions reach or are outside a predetermined allowable envelope. Scramming the reactor stops the fission process by rapidly inserting control rods. Failure of the RTS system can lead to a transient or accident without a scram. While such events are not a design basis accident, the probability and consequences of such a situation have been analyzed. The accident sequences which describe such situations are referred to as Anticipated Transients Without Scram (ATWS)

For design basis accidents, the RTS will successfully scram the reactor because the system meets the single failure criteria. The proposed changes do not affect the way in which the system meets the single failure criteria.

The proposed changes would not change the analyzed consequences of an ATWS since the consequences are based on an assumed failure of the RTS to stop the fission process. The proposed

changes would not change this assumed failure.

The proposed changes do not significantly increase the probability of an RTS failure. WCAP-10271 and Supplement 1 evaluated the increases in ATWS probability for the four changes proposed by WCAP-10271 on a generic basis. Sensitivity analyses were used to examine the effects of each of the four changes. WCAP-10271 concluded that the changes in probability were very small. For Callaway, only three of the four changes addressed in WCAP-10271 are being requested—those related to surveillance interval, maintenance time, and test time. The change related to testing in bypass is not being proposed for Callaway.

In its February 21, 1985 Safety Evaluation Report addressing WCAP-10271, the NRC also concluded that the increase in probability of RTS failure due to the four proposed changes was very small and not significant.

The sensitivity analyses demonstrate that some increased probability is associated with each of the changes. However, the overall probability for all four of the changes proposed by WCAP-10271 was judged by the NRC not to be significant. The proposed subset of only three of those changes, would result in a smaller increased probability than all four WCAP-10271 changes. Therefore, the increased probability associated with the three changes proposed for Callaway would also not be significant.

Criterion 2—The proposed license amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The four changes proposed in WCAP-10271 affect only the amount of time during which individual RTS channels may be unavailable and the frequency of testing of the RTS channels. The Technical Specifications presently allow the unavailability of individual channels for short periods of time, Changes in the allowed unavailability times and test intervals do not create a new failure mechanism; they only affect the probability of that failure as discussed under Criterion 1. As explained under Criterion 1, failures of the RTS have been analyzed.

Since none of the changes proposed by WCAP-10271 create new failure mechanisms, the changes proposed for Callaway (which are a subset of the WCAP-10271 changes) would not create new failure mechanisms.

Criterion 3—The proposed license amendment does not involve a significant reduction in a margin of safety. The proposed changes do not alter any safety limits or limiting safety system settings, nor do the changes reduce the requirements for the number

of operable RTS channels.

As explained above under Criteria 1 and 2, the changes proposed by WCAP-10271 only affect the test intervals and allowed unavailable times for the RTS channels, and the increase in the probability of RTS failure due to the proposed changes is not significant. In the Febrary 21, 1985 SER the NRC concluded that the resultant increase in the overall plant risk of core damage was not significant.

Since the changes proposed for Callaway are a subset of the WCAP-10271 proposal, the resultant increase in overall plant core damage risk would be smaller than the increase for the four WCAP-10271 changes. Therefore, the overall reduction in plant margin of safety is not significant for the three changes proposed for Callaway.

Accordingly, the Commission proposes to determine that these changes do not involve a significant

hazards consideration.

Local Public Document Room location: Fulton City Library, 709 Market Street, Fulton, Missouri 65251 and the Olin Library of Washington University, Skinker and Lindell Boulevards, St. Louis, Missouri 63130.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts and Trowbridge, 1800 M Street, NW., Washington, DC 20036.

NRC Project Director: B.J. Youngblood.

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of amendment request: January 3, 1986.

Description of amendment request: The purpose of the proposed amendment is to revise Callaway Technical Specification Figure 6.2-1, Figure 6.5.1.2, and sections 6.5.2.2, 6.5.2.7 and 6.5.3.1 to reflect administrative and organizational changes associated with the establishment of the positions of General Manager, Nuclear Operations; and Manager, Operations Support; and resulting changes in the operating organization, engineering organization, On-Site Review Committee and Nuclear Safety Review Board. Also included in the change is the deletion of the position of Advisor to the Manager, Callaway Plant, and the deletion of the Nuclear Construction Department.

Basis for proposed no significant hazards consideration determination: The Commission has provided guidance concerning the application of the

standards in 10 CFR 50.92 by providing certain examples (51 FR 7744). One of the examples (i) of these actions involving no significant hazards consideration relates to a purely administrative change to Technical Specifications. Another example (ii) involving no significant hazards consideration is a change which constitutes an additional limitation, restriction or control not presently included in the Technical Specifications. The proposed changes are similar in nature to the examples provided by the Commission. The changes to the Callaway Technical Specifications revise Figure 6.2-1, Figure 6.2-2 and sections 6.5.1.2, 6.5.2.2, changes associated with the establishment of the positions of General Manager, Nuclear Operations and Manager, Operations Support and the resulting changes in the operating organization, engineering organization, On-Site Review Committee and Nuclear Safety Review Board. Although personnel assignments are revised and reporting relationships are changed, the commitments to minimum qualifications and basic organizational reporting requirements are unchanged. These proposed changes are administrative in nature and introduce additional management controls not presently in the Technical Specifications and, therefore, involve no significant hazards. These requests do not involve a significant increase in the probability or consequence of an accident or other adverse condition over previous evaluations; or create the possibility of a new or different kind of accident or condition over previous evaluations; or involve a significant reduction in a margin of safety. Based on this information, the requested license amendment does not present a significant hazard.

Local Public Document Room location: Fulton City Library, 709 Market Street, Fulton, Missouri 65251 and the Olin Library of Washington University, Skinker and Lindell Boulevards, St. Louis, Missouri 63130.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts & Trowbridge, 1800 M Street, NW., Washington, DC 20036.

NRC Project Director: B.J. Youngblood.

Virginia Electric and Power Company, Docket Nos. 50–338 and 50–339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of amendment request: June 30, 1986.

Description of Amendment Request: The proposed changes would revise the NA-1 TS, section 4.7.14, Surveillance Requirements for the Fire Suppression Systems, by increasing the frequency for fire pump diesel engine surveillance and would delete a portion of the required surveillance for the fire pump diesel starting 24 volt battery bank and charger for NA-1&2.

The NA-1&2 fire protection system is designed to furnish water and other extinguishing agents with the capability of extinguishing any single or probable combination of simultaneous fires that might occur at NA-1&2. A diesel-enginedriven fire pump and a motor driven fire pump are available to supply water for the sprinklers and hose streams. The capacity of each fire pump has been established such that either pump can provide 100% of the required capacity. The diesel-engine-driven fire pump is equipped with an automatic controller starting on low fire protection system pressure. A separate manual operator is also available to start the engine in the event the controller malfunctions. The engine is started by a 24 volt cranking motor. Power for this motor is obtained from either of two 24 volt storage batteries.

TS 4.7.14.1.2.c.2 for NA-1 requires that the fire pump diesel engine shall be demonstrated OPERABLE at least once per 18 months (during shutdown) by verifying the diesel starts from ambient conditions on the auto start signal and operates for greater than or equal to 20 minutes while loaded with the fire pump. The proposed change would require that this surveillance be performed at least once per 31 days (instead of once per 18 months) and that the engine operate for at least 30 minutes (instead of greater than or equal to 20 minutes). The actual engine surveillance is being performed as described by the proposed change because this more stringent surveillance is already required by the NA-2 TS 4.7.14.1.2.A.2. Hence, this change would make the surveillance requirements consistent for both units since the engine is part of a shared system for NA-1&2.

TS 4.7.14.1.3.c.1 for NA-1&2 requires that the fire pump diesel starting 24 volt battery bank and charger shall be demonstrated OPERABLE at least once per 18 months by verifying that the batteries, cell plates and battery racks show no visual indication of physical damage or abnormal deterioration. The proposed change would limit the surveillance requirements to the batteries and the battery racks. The proposed change would delete the requirement to visually inspect the battery cell plates because this inspection is somewhat limited in scope

since the battery case is opaque and the only visual access to the cell plates is provided by removing the battery caps. As a result, this particular surveillance is of limited value. Additionally, this inspection is not required by the National Fire Protection Association.

The other surveillance requirements for the battery bank include verifying that: (1) The electrolyte level of each battery is above the plates (once per 7 days), (2) the overall battery voltage is greater than or equal to 24 volts (once per 7 days), (3) the specific gravity is appropriate for continued service of the battery (once per 92 days), and (4) the battery-to-battery and terminal connections are clean, tight, free of corrosion and coated with anti-corrosion material (once per 18 months).

Additionally, the NA-2 TS 4.7.14.1.2 requires that the diesel engine be started at least once per 31 days. This is currently a requirement for the NA-2 TS and is being proposed as a requirement for the NA-1 TS. This surveillance not only demonstrates the operability of the diesel engine, but also directly demonstrates the operability of the batteries since the batteries supply the power to start the engine. This battery functional verification together with the remaining battery surveillance requirements described above are sufficient to demonstrate the operability of the fire pump diesel starting 24 volt battery bank.

Basis for proposed no significant hazards consideration determination: The Commission has provided guidance concerning the application of these standards by providing certain examples which were published in the Federal Register on April 6, 1983 (48 FR 14870). Example (ii) is a change that constitutes an additional limitation. restriction or control not presently included in the TS; for example, a more stringent surveillance requirement. Also, the Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR Part 50.92(c). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) Involve a significant reduction in a margin of safety

The proposed change for NA-1 TS 4.7.14.1.2.C.2 is enveloped by the Commission's example (ii) since the change reflects the current and more

stringent requirement specified for the NA-2 TS which have been approved and is consistent with the guidance provided in NUREG-0452, Revision 4, "Westinghouse Standard Technical Specifications for Light Water Reactors." Based on the discussion above, the proposed change for the NA-1&2 TS 4.7.14.1.3.C.1 would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated because the proposed change does not adversely affect the operability of the batteries. (2) create the possibility of a new or different kind of accident from any 1 accident previously evaluated because it does not involve any change to the physical plant and does not introduce any new or unique operational modes or accident precursors, and (3) involve a significant reduction in a margin of safety because it does not adversely affect the operability and performance of the batteries.

Thus, the proposed changes as discussed above are either enveloped by example (ii) as published in the Federal Register (48 FR 14870) or by the criteria specified in 10 CFR Part 50.92(c). Therefore, the NRC staff proposes to determine that the standards for determining that the proposed changes involve no significant hazards considerations are met, and that operation of the facility in accordance with the proposed changes would not involve a significant hazards consideration.

Local Public Document Room location: Board of Supervisors Office, Louisa County Courthouse, Louisa, Virginia 23093 and the Alderman Library, Manuscripts Department, University of Virginia, Charlottesville, Virginia 22901.

Attorney for licensee: Michael W. Maupin, Esq., Hunton, Williams, Gay and Gibson, P.O. Box 1535, Richmond, Virginia 23212.

NRC Project Director: Lester S. Rubenstein.

NOTICE OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE

During the period since publication of the last bi-weekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10

CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing in connection with these actions was published in the Federal Register as indicated. No request for a hearing or petition for leave to intervene was filed following this notice.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendments, (2) the amendments, and (3) the Commission's related letters, Safety Evaluations and/or Environmental Assessments as indicated. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC. and at the local public document rooms for the particular facilities involved. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Licensing.

Arkansas Power & Light Company, Docket No. 50–368, Arkansas Nuclear One, Unit 2, Pope County, Arkansas

Date of Application for Amendment: April 1, 1986.

Brief Description of Amendment: The amendment revised Surveillance Requirement 4.8.2.3.1.a.2 to allow replacement of a bank of the station batteries.

Date of Issuance: July 11, 1986. Effective Date: July 11, 1986. Amendment No.: 75.

Facility Operating License No. NPF-6: Amendment revised the Technical Specifications.

Date of Initial Notice in Federal Register: June 10, 1986 (51 FR 21032). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 11, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room Location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Carolina Power and Light Company, Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: December 11, 1985, as supplemented by letters dated May 1, 1986, June 18, 1986, and June 27, 1986.

Brief description of amendment: The amendment revises the Technical Specification to add operational and surveillance criteria for the use and capabilities of the containment purge supply and exhaust isolation valves.

Date of issuance: July 3, 1986. Effective date: July 3, 1986. Amendment No.: 99.

Facility Operating License No. DPR-23: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: February 26, 1986 (51 FR 6820). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 3, 1986. No significant hazards consideration comments received: No

Local Public Document Room location: Hartsville Memorial Library, Home and Fifth Avenues, Hartsville, South Carolina 29535.

Connecticut Yankee Atomic Power Company, Docket No. 50–213, Haddam Neck Plant, Middlesex County, Connecticut

Date of application for amendment: May 14, 1986.

Brief description of amendment: The amendment permits the performance of monthly surveillance tests on valve SI-MOV-24 (on the line from the refueling water storage tank) and on valve RH-MOV-874 (on the residual heat removal system pump discharge). The monthly surveillance tests on the subject valves are required to assure the operability of a high pressure recirculation cooling mode following a certain range of small line break loss-of-coolant accidents.

Date of issuance: July 11, 1986. Effective date: July 11, 1986. Amendment No.: 77.

Facility Operating License No. DPR-61: Amendment revised the technical specifications.

Date of initial notice in Federal Register: June 4, 1986 (51 FR 20369). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 11, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Russell Library, 124 Broad Street, Middletown, Connecticut 06457.

Connecticut Yankee Atomic Power Company, Docket No. 50–213, Haddam Neck Plant, Middlesex County, Connecticut

Date of application for amendment: December 6, 1985 as modified January 7,

Brief description of amendment: This amendment modifies the current technical specifications (1) to permit the repair of degraded steam generator tubes by installing metal sleeves in the degraded tubes rather than removing them from service by plugging them, (2) to change the definition of tube degradation, (3) to add additional reporting requirements dealing with tube sleeving, and (4) to renumber existing technical specification pages.

Date of issuance: July 14, 1986. Effective date: July 14, 1986. Amendment No.: 78.

Facility Operating License No. DPR-61: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: January 29, 1986 (51 FR 3713). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 14, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Russell Library, 124 Broad Street, Middletown, Connecticut 06457.

Consumers Power Company, Docket No. 50–155, Big Rock Point Plant, Charlevoix County, Michigan

Date of application for amendment: May 1, 1986.

Brief description of amendment: The amendment adds a sentence to the minimum requirements for shift crew composition allowing the designation of the control room shift command function.

Date of issuance: July 11, 1986. Effective date: July 11, 1986. Amendment No.: 86.

Facility Operating License No. DPR-6: This amendment revised the Technical Specifications.

Date of initial notice in Federal Register: June 4, 1986 (51 FR 20369). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 11, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: North Central Michigan College, 1515 Howard Street, Petoskey, Michigan 49770. Dairyland Power Cooperative, Docket No. 50–409, La Crosse Boiling Water Reactor, Vernon County, Wisconsin Date of application for amendment:

February 21, 1986.

Brief description of amendment: The amendment changes the functional test and calibration frequencies for installed area radiation monitors from every 2 weeks to quarterly, and from each refueling outage to at least once per 18 months, respectively.

Date of Issuance: July 15, 1986. Effective date: July 15, 1988. Amendment No.: 49.

Provisional Operating License No. DPR-45: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: May 7, 1986 (51 FR 16926). The Commission's related evaluation for the license amendment is contained in a Safety Evaluation dated July 15, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: La Crosse Public Library, 800 Main Street, La Crosse, Wisconsin 54601.

Florida Power Corporation, et al., Docket No. 50–302, Crystal River Unit No. 3 Nuclear Generating Plant, Citrus County, Florida

Date of application for amendment: April 23, 1984.

Brief description of amendment: This amendment revises the reporting requirements of the Technical Specifications to bring them into conformance with the revision to 10 CFR 50.72 and with 10 CFR 50.73.

Date of issuance: July 17, 1986. Effective date: July 17, 1986. Amendment No.: 90.

Facility Operating License No. DPR-72: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: November 21, 1984 (49 FR 45948). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 17, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room Location: Crystal River Public Library, 668 NW. First Avenue, Crystal River, Florida 32629.

Florida Power and Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Date of application for amendments: April 15, 1986.

Brief description of amendments: These amendments revise the design section of the Technical Specifications to allow the use of burnable poisons that are not in the form of discrete rod clusters but are integral to the fuel rods. This feature is known as the Integral Fuel Burnable Absorber (IFBA). The IFBA design has been demonstrated through test assemblies to perform as predicted.

Date of issuance: July 14, 1986. Effective date: July 14, 1986. Amendment Nos. 117 and 111 Facility Operating Licenses Nos. DPR-31 and DPR-41: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: May 21, 1986 (51 FR 18682). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 14, 1986.

No significant hazards consideration comments received: No

Local Public Document Room location: Environmental and Urban Affairs Library, Florida International University, Miami, Florida 33199.

GPU Nuclear Corporation, Docket No. 50-219, Oyster Creek Nuclear Generating Station, Ocean County, New

Date of application for amendment:

April 14, 1986 (TSCR 143).

Brief description of amendment: This amendment authorized a change to the Appendix A Technical Specifications (TS) pertaining to the surveillance of the excess flow check valves (EFCV) in instrument lines penetrating containment. This change is to TS 4.5.0 in section 4.5, Containment, of the TS. This change revised the conditions requiring open position verification of the EFCV before an instrument line is returned to service. The revision is to (1) delete the condition of isolating an instrument, (2) delete the condition of venting an isolated instrument or instrument line, (3) retain the condition of venting an unisolated instrument or instrument line, and (4) add the condition of adding a new instrument or instrument line.

Date of issuance: July 9, 1986. Effective date: 60 days after the date of issuance.

Amendment No.: 104. Provisional Operating License No. DPR-16: Amendment revised the Technical Specifications. Date of initial notice in Federal

Register: May 21, 1986 (51 FR 18684). The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated July 9, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Ocean County Library, 101 Washington Street, Toms River, New Jersey 08753.

GPU Nuclear Corporation, Docket No. 50-219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey

Date of application for amendment: June 4, 1985.

Brief description of amendment: This amendment authorizes a change to the license which would extend the date imposed by Order of March 14, 1983, to fully implement NUREG-0737 Item III.D.3.4, Control Room Habitability, from the Cycle 11 Refueling outage to the Cycle 12 Refueling outage.

Date of issuance: July 15, 1986. Effective date: July 15, 1986. Amendment No.: 105.

Provisional Operating License No. DPR-16: Amendment revised the license.

Date of initial notice in Federal Register: December 18, 1985 (50 FR 51623).

The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated July 15, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Ocean County Library, 101 Washington Street, Toms River, New Jersey 08753.

GPU Nuclear Corporation, Docket No. 50-219, Oyster Creek Nuclear Generating Station, Ocean County, New

Date of application for amendment: September 19, 1985

Brief description of amendment: This amendment authorized a revision to the requirement in Confirmatory Order dated March 14, 1983, to install interlocks on the recirculation pump loops at Oyster Creek to prevent isolating four recirculation loops. The licensee will install an alarm to indicate that a fourth recirculation loop has been isolated instead of electrical interlocks to prevent isolation of more than three recirculation loops. This revision does not change the schedule in the Order to implement the modification to the recirculation loops. The alarm must be installed, the procedures written to use the alarm, and the operators trained, before the restart from the Cycle 11 Refueling outage. The restart is scheduled for October 1986.

Date of issuance: July 15, 1986. Effective date: July 15, 1986. Amendment No.: 106.

Provisional Operating License No. DPR-16: Amendment revised the license.

Date of initial notice in Federal Register: April 23, 1986 (51 FR 15397).

The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated July 15, 1996.

No significant hazards consideration comments received: Yes.

On May 19, 1986, the State of New Jersey was consulted in accordance with 10 CFR 50.91(b)(4). The State expressed its concern that the staff was not imposing the requirements in the Order. This is addressed in the Safety Evaluation attached to the amendment. The staff concluded that the alarms only modification and trained operators will have the same effect as the interlock without the complexity introduced by the interlock.

Local Public Document Room location: Ocean County Library, 101 Washington Street, Toms River, New Jersey 08753.

GPU Nuclear Corporation, Docket No. 50-219, Oyster Creek Nuclear Generating Station, Ocean County, New

Date of application for amendment: February 3, 1986.

Brief description of amendment: This amendment authorizes changes to sections 1, 2, 3, and 4 of the Appendix B, **Environmental Technical Specifications** (TS) pertaining to Definitions, Environmental Monitoring, Special Monitoring and Study Activities, and Administrative Controls, respectively. These changes revise or delete the following: (a) revise the table of contents, (b) delete the list of tables and figures, (c) delete the definitions, (d) delete the introducing paragraph in section 2.1, (e) delete Table 2-1 and 2-2, (f) delete section 2.1.1.A, Impingement of Organism, (g) revise section 2.1.1.B, Fish Kill Monitoring Program, (h) delete section 3.1, Woodborer Monitoring Program, (i) delete the second paragraph in section 3.2, Unusual or Important Environmental Events, (j) revise section 4.1, Responsibility, Administrative Controls, and Figure 4-1 for new titles. (k) delete reference to section 4.4.3 in items F and H of section 4.3, Review and Audit, Administrative Controls, (1) revise section 4.4.1 and delete sections 4.4.2 and 4.4.3, Procedures, (m) revise item 1 of section 4.5.1.A, Routine Reports, and (n) revise the page numbers of the TS.

Date of issuance: July 17, 1986. Effective date: July 17, 1986. Amendment No.: 107.

Provisional Operating License No. DPR-16: Amendment revised the Appendix B Technical Specifications.

Date of initial natice in Federal

Date of initial notice in Federal Register: March 12, 1986 (51 FR 8594).

The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated July 17, 1986.

No significant hazards consideration

comments received: No.

Local Public Document Room location: Ocean County Library, 101 Washington Street, Toms River, New Jersey 08753.

Niagara Mohawk Power Corporation, Docket No. 50–220, Nine Mile Point Nuclear Station, Unit No. 1, Oswego County, New York

Date of amendment request: May 27, 1986.

Brief description of amendment: The amendment modifies Technical Specification (TS) section 6.12, High Radiation Area, Table 3.6.2a, Instrumentation That Initiates Scram, Table 3.6.2b, Instrumentation That Initiates Primary Coolant System or Containment Isolation, Table 3.6.2h, Vacuum Pump Isolation, and the notes to these three tables to allow Niagara Mohawk to demonstrate the feasibility of a Hydrogen Water Chemistry System as a mitigator of intergranular stress corrosion cracking of stainless steel piping at Nine Mile Point Unit 1.

Date of issuance: July 10, 1986. Effective date: July 10, 1986. Amendment No.: 87.

Facility Operating License No. DPR-63: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: June 9, 1986 (51 FR 20902); June 16, 1986 (51 FR 21813). The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated July 10, 1986.

No significant hazards consideration

comments received: No.

Local Public Document Room location: State University of New York, Penfield Library, Reference and Documents Department, Oswego, New York 13126.

Southern California Edison Company et al., Docket No. 50–206, San Onofre Nuclear Generating Station, Unit No. 1, San Diego County, California

Date of application for amendment: February 14, 1985.

Brief description of amendment: The amendment incorporates load limitations for emergency diesel engine testing and modifies the monthly surveillance test conditions and the duration of the 18-month test run.

Date of issuance: July 3, 1986.

Effective date: July 3, 1986. Amendment No.: 95.

Provisional Operating License No. DPR-13. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: March 27, 1985 (50 FR 12163). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 3, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Main Library, University of California, P.O. Box 19557, Irvine, California 92713.

Wisconsin Public Service Corporation, et al., Docket No. 50–305, Kewaunee Nuclear Power Plant, Kewaunee County, Wisconsin

Date of application for amendment: September 24, 1985 and as revised October 9, 1985.

Brief description of amendment: The amendment removes a limiting condition for operation upon completion of the rerouting of the Kewaunee offsite power source transmission lines.

Date of issuance: July 3, 1986.
Effective date: This license
amendment is effective as of the date
the rerouted transmission lines are
declared operable.

Amendment No.: 67.

Facility Operating License No. DPR-43: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: December 4, 1985 (50 FR 49795). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 3, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: University of Wisconsin Library Learning Center, 2420 Nicolet Drive, Green Bay, Wisconsin 54301.

Wisconsin Public Service Corporation, et. al. Docket No. 50-305, Kewaunee Nuclear Power Plant, Kewaunee County, Wisconsin

Date of application for amendment: April 15, 1986.

Brief description of amendment: This amendment changes the frequency of loading the diesel generators to their short-term rating from once each month to once each refueling cycle.

Date of issuance: July 10, 1986. Effective date: July 10, 1986. Amendment No.: 68.

Facility Operating License No. DPR-43. Amendment revised the Technical Specifications. Date of initial notice in Federal Register: May 7, 1986 (51 FR 16919– 16935). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 10, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: University of Wisconsin Library Learning Center, 2420 Nicolet Drive, Green Bay, Wisconsin 54301.

Wisconsin Electric Power Company, Docket Nos. 50–266 and 50–301, Point Beach Nuclear Plant, Unit Nos. 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin

Date of application for amendments: March 5, 1986.

Brief description of amendments: The amendments revise the Technical Specifications for reporting requirements relating to primary coolant activity levels due to iodine spikes. They also delete the requirement to shutdown the reactor if primary coolant activity levels exceed 1.0 microcuries per gram (Dose Equivalent I-131) for 800 hours during any consecutive 12-month period.

Date of issuance: June 27, 1986.

Effective date: 20 days from date of issuance.

Amendment Nos.: 102 and 105.
Facility Operating License Nos. DPR-24 and DPR-27. Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: May 21, 1986 (51 FR 18676– 18697). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 27, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Joseph P. Mann Library, 1516 Sixteenth Street, Two Rivers, Wisconsin.

Wisconsin Electric Power Company, Docket Nos. 50–266 and 50–301, Point Beach Nuclear Plant, Unit Nos. 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin

Date of application for amendments: April 10, 1985 and modified February 14, and March 10, 1986.

Brief description of amendments: The amendments revise the Point Beach Nuclear Plant, Unit 1 and 2 Technical Specifications by adding more restrictive conditions to the limiting conditions for operation for reactor coolant pumps. The amendments ensure that at least one reactor coolant pump will be running with the reactor critical and both reactor coolant pumps will be

required to be running above 3.5% reactor power. The appropriate bases also have been changed and an administrative error concerning a reference to the Final Safety Analysis Report has been corrected.

Date of issuance: July 3, 1986.

Effective date: 20 days from the date of issuance.

Amendment Nos.: 103 and 106.
Facility Operating License Nos. DPR-24 and DPR-27. Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: July 31, 1985 (50 FR 31061– 31076). Renoticed March 26, 1986 (51 FR 10451–10471). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 3, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Joseph P. Mann Library, 1516 Sixteenth Street, Two Rivers, Wisconsin.

Dated at Bethesda, Maryland, this 23rd day of July, 1986.

For the Nuclear Regulatory Commission.
Thomas M. Novak.

Acting Director, Division of PWR Licensing— A, Office of Nuclear Reactor Regulation. [FR Doc 86–17005 Filed 7–29–86; 8:45 am] BILLING CODE 7590–01–M

[Docket No. 50-322-OL-5; ASLBP No. 86-533-01-OL]

Long Island Lighting Co.; Shoreham Nuclear Power Station, Unit 1 (EP Exercise); Change of Docket Number

In response to motions filed by Applicant and Intervenors in Long Island Lighting Company (Shoreham Nuclear Power Station, Unit 1), Docket No. 50–322–OL–3, the Commission, in a Memorandum and Order, CLI–86–11, 23 NRC ________1986, issued June 6, 1986, directed the immediate initiation of the exercise hearing to consider evidence which Intervenors might wish to offer to show that there is a fundamental flaw in Applicant's emergency plan.

The Atomic Safety and Licensing Board Panel, by Order of June 10, 1986, designated an Atomic Safety and Licensing Board to preside in this matter, which containued to bear Docket No. 50–322–OL–3, issued for the emergency planning proceeding. For more effective docket management, it is necessary to assign a new docket number for this phase of the application proceeding. It is hereby ordered that the docket number to be used henceforth for the proceeding instituted by the

Commission on June 6, 1986, is Docket No. 50-322-OL-5 (EP Exercise).

Issued at Bethesda, Maryland, this 24th day of July, 1986.

B. Paul Cotter, Jr.,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 86-17121 Filed 7-29-86; 8:45 am] BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-23461; File No. SR-Amex-86-21, SR-Phix-86-22, and SR-CBOE-86-21]

Self-Regulatory Organizations; American Stock Exchange, Inc., et al.; Order Granting Accelerated Effectiveness of Proposed Rule Changes

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 23, July 7, and 17, 1986, respectively, the American ("Amex") and Philadelphia ("Phlx") Stock Exchanges and the Chicago Board Options Exchange, Incorporated ("CBOE"), filed with the Securities and Exchange Commission the proposed rule changes described in Items I, II, and III below, which Items have been prepared by the self-regulatory organizations. The Commission is publishing this notice to solicit comments on the proposed rule changes from interested persons.

I. Self-Regulatory Organizations' Statement of the Terms of Substance of the Proposed Rule Changes

The above referenced exchanges proposed to extend for an additional six months their stock options pilot programs which provide for four expiration months—including two near-term months. The details of the proposal are set forth below in Item 3.

II. Self-Regulatory Organizations' Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

In their filings with the Commission, the self-regulatory organizations included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments they received on the proposed rule changes. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organizations have prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organizations' Statement of the Purpose of and Statutory Basis for, the Proposed Rule Changes

In June 1985, the Amex, Phlx, and CBOE all implemented a uniform option expiration pilot program. Under the terms of the pilot program, for certain January cycle stock options, (a) onemonth and two-month options were made available for trading at all times, and (b) the farthest-term expiration month was added one month later than it was added pursuant to the traditional January trading cycle. Thus, four expiration months were outstanding at any time.

The purpose of the pilot program was to determine whether a modified, near-term expiration cycle, featuring four expiration months, would enhance investors' interest in options on individual stocks.² After Monitoring the trading volume of those stock options subject to the pilot program and having received a preponderance of favorable comments from both on-floor and off-floor options professionals,³ the Exchanges have found that the pilot on balance has improved trading volume.

Accordingly, the exchanges propose to extend the pilot for an additional six months. The Amex and Phlx intend to add the January cycle stock options to the pilot as follows: After the July expiration, September 1986 and April 1987 series will be added to the October 1986 and January 1987 series already outstanding. 4 Thus, September, October, January and April series will be outstanding. By adding new options to the pilot as described in the preceding paragraph, the exchanges believe it will provide more opportunity for investors interest to develop in the near series.

In addition, the Amex and Plex seek to incorporate all of their respective January cycle stock options into the pilot on the first business day after the expiration of July options contracts. The exchanges have not determined when

¹ See Securities Exchange Act Release No. 22099. (May 31, 1985), 50 FR 23862 (June 6, 1985).

^a The Exchange previously had used a similar expiration cycle of index options and believed that monthly expiration had contributed to investor interest in those options.

³ The Commission has received one adverse comment regarding the pilot program. See discussion infra. Section II C.

⁴ The exchanges are not including an August expiration because the believe there would be insufficient open interest in two consecutive one month options (e.g., August and September). The exchanges believe it would be beneficial to allow open interest to develop over a two month period and have, therefore, proposed to re-commence the pilot beginning with a September expiration.

they will phase in February and March cycle stock options.

The proposed rule changes are consistent with the requirements of the Securities Exchange Act of 1934 ("1934 Act") and the rules and regulations thereunder applicable to national securities exchanges by continuing a pilot program tailored to meet investor preferences for stock options with nearterm expiration cycles. Therefore, the proposed rule changes are consistent with Section 6(b)(5) of the 1934 Act, which provides in pertinent part, that the rules of the exchanges be designed to promote just and equitable principles of trade and to protect the investing public.

B. Self-Regulatory Organization's Statement on Burden on Competition

The exchanges believe that the proposed rule changes will not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Changes Received from Members, Participants, or Others

The Amex and Phlx Options Committees⁵ and the CBOE's Product Development Committee⁶ have endorsed the proposed rule change.

The Amex and Phlx report that while no written comments were solicited or received by them, the exchanges received numerous favorable oral comments from specialists who have specialty options currently included in the pilot, Registered Options Traders and personnel from member firm options departments. Amex specifically has stated that its Marketing Department contacted at least 45 Amex member firms to inform them of the proposed pilot extension and received no adverse comments.

CBOE reports that in a survey of representatives of six member firms, it received favorable comments on the pilot. The only market-related reservation was that two commentators felt that a floor wide expansion of the pilot could result in more cyclical trading of options, if all options in the pilot would be on the same expiration cycle.

CBOE also states that questions were raised concerning tax effects of the pilot. Under the pilot, which opens options for trading eight months from expiration rather than the traditional nine months,

there are time periods when there is not an option which can be held for long term capital gain treatment. CBOE states that it does not believe that this motivation alone is sufficient to redesign the pilot program at this time. During the continuation of the pilot, CBOE has stated that it will examine pilot trading activity to gauge if long-term trading would increase activity significantly or otherwise enhance the depth and liquidity of long-term options.

The Commission received one adverse letter of comment regarding the proposed six month extension of the pilot.7 This commentator voiced four concerns regarding extension of the pilot. First, the commentator questioned the need for a six month extension to further study the pilot's success or lack thereof. The exchanges, in response, have stated that the decision to file for an extension of the pilot and not permanent approval was based, in part, on the current status of proposed federal tax legislation. Certain provisions of pending federal tax legislation, if approved, could cause the exchanges to reevaluate the utility of monthly expiration cycles. The exchanges do not wish to request permanent approval of the program when significant changes may be made in the near future.

The commentator's second concern regards investor confusion. Because newspapers currently do not print the fourth expiration month of those options now trading in the pilot, the commentator argues that investors, currently familiar with quarterly expirations, will not be aware of the

newer monthly cycles.

In response, the Amex has stated that it has encountered little evidence of investor confusion in its relatively broad survey of member firms.8 Further, Amex states that it and the other exchanges are working with the press to develop improved coverage of the revised expiration cycle. A related concern regards possible quotation vendor or back office problems resulting from the greatly increased number of strike prices which exist at one time given the inclusion of a fourth month on the January cycle. In this regard, the exchanges state that vendors and member firms have experienced no

7 Letter from Harrison Roth, Drexel Burnham Lambert, Inc., to Brandon Becker, Assistant Director, Division of Market Regulation, dated July 14, 1986

significant problems. The exchanges state that they do not anticipate such developing in the future.

The third concern results from the fact that shifting to a four month cycle will eliminate nine month options, which will, in turn, eliminate six month options approximately 1/3 of the time. This could, at times deprive investors of the availability of long term options, the profit from which would receive long term capital gain treatment.

The exchanges state that they have taken note of this concern but have made business judgments that investor preference for two short term months demonstrated by higher liquidity in these months) outweighs the need for a six month option.

Finally, the commentator contends that the public has not had the benefit of sufficient time to adapt to or comment on the pilot. In this regard, the Commission notes that this pilot has been in existence now for a year, during which time the exchanges have experienced virtually no problems with public adaptation to the revised cycle. In fact, the heightened volume and favorable public comment indicate that the program has been successful.

III. Date of Effectiveness of the Proposed Rule Changes and Timing for **Commission Action**

The exchanges request that the proposed rule change be given accelerated effectiveness pursuant to section 19(b)(2) of the 1934 Act to enable them to implement the proposals on the first business day after the July expiration and continue the pilot program without interruption.

The Commission finds that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges, and in particular, the requirements of Section 6 and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule changes prior to the thirtieth day after the date of publication of notice of filing thereof. As originally approved, the monthly expiration pilot contemplated that the exchanges would be able to add additional options classes as they deemed appropriate.9 Accordingly, a six-month extension of the pilot essentially allows those exchanges to keep in place a pilot program which the

^{*} It should be noted that investor confusion was addressed in the original filing which established the monthly expiration pilot. Investor confusion was deemed to be minimized by having an eight month rather than nine month expiration series which ensures that a constant number (four) of monthly expiration cycles will remain open simultaneously. See footnote, 1, supra. p. 2.

⁵ The Amex and Phlx Committees are committees of the respective exchanges' Board of Governors, composed of members and representatives of member firms.

⁶ CBOE's Product Development Committee is composed of individual members and representatives of member firms.

⁹ See Securities Exchange Act Release No. 22099. (May 31, 1985) 50 FR 23862 (June 6, 1985).

exchanges have found, on balance, to be successful. Moreover, to the extent concerns have been raised which might generally effect investors (e.g., the absence of full newspaper coverage or certain expiration months for tax trading purposes), the exchanges have indicated that they are working to address those concerns and believe that extension of the pilot will provide them with an opportunity to assess the significance of those concerns. Moreover, except for the one adverse comment received by the Commission, the exchanges have represented that their memberships are generally supportive of the pilot and do not believe that the pilot should be interrupted at this time. Finally, accelerated approval of the proposals will enable the exchanges to continue the pilot without interruption for another six months, during which time they may decide whether to request permanent approval of the program.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW. Washington, DC 20549. Copies of the submission, all amendments, all written statements with respect to the proposed rule changes that are filed with the Commission, and all written communications relating to the proposed rule changes between the Commission and any person, other than those may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing also will be available for inspection and copying at the principal office of the above-mentioned self-regulatory organizations. All submissions should refer to the file numbers in the caption above and should be submitted within 21 days after the date of this publication.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: July 23, 1986.

Jonathan G. Katz, Secretary.

[FR Doc. 86-17068 Filed 7-29-86; 8:45 am]
BILLING CODE 8010-01-M

[Release No. 34-23453; File No. SR-CBOE-86-17]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Filing and Order Granting Accelerated Approval To Proposed Rule Change

On June 19, 1986, the Chicago Board Options Exchange, Inc. ("CBOE") submitted to the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) under the Securities Exchange Act of 1934 ("Act") 1 and Rule 19b—4 thereunder, 2 a proposed rule change that increases the monthly allocations in its foreign currency options incentive program that provides financial credits to market makers based on the number of their off-floor orders.

On May 7, 1986, the Commission approved a six-month currency options incentive program for the period March 3 through August 29, 1986.3 Under the program, the CBOE computes for each market maker, from trade match data in each currency class, the total number of in-person, market maker trades made with off-floor orders. Based on this information, incentive credits are allocated among market makers for each options class. These credits can be applied by the market maker toward the payment of dues, fees and open market seat purchases. The program provides that during the entire six-month program, the monthly total of incentive credits will not be more than \$120,000 for all currency options classes.

CBOE is proposing to increase the monthly allocations for June, July and August from \$120,000 to \$300,000. In its filing, the CBOE also imposes the following monthly limits on credits allowed for each currency options class: \$75,000 each for Japanese yen and West German marks, \$50,000 each for Swiss francs and Canadian dollars and \$25,000 each for British pounds and French francs.

The CBOE has stated that the purpose of the increase is to encourage the continued presence of market makers in the foreign currency options trading crowd. According to the CBOE, because market makers presently trading currency options have given up more predictable revenues in other more established options markets, the increased incentive credits should help defray some of the costs as market makers attempt to establish this new

market. CBOE also states that another purpose for the increased incentives is to attract additional market makers to the currency options trading crowd.

In the Commission's original approval order, we noted concern that an incentive program designed to provide dollar credits (that can be applied to dues and fees) based on a market maker's volume in foreign currency options could encourage so-called "chumming" 4 or other artificial forms of trading by which market makers might attempt to inflate their volume in order to earn the credits.

The Commission, however, decided to approve the limited six month program because, among other things, the CBOE indicated that it would monitor foreign currency options market makers doing a large accommodation volume to ensure that this volume consisted of actual accommodations that should be counted towards the market maker's credits. The CBOE has indicated that, to date, no abuses involving chumming or prearranged trading has been found in CBOE's foreign currency options market. Although an increase in the allocated credits may create greater incentives for such abuses, the Commission believes that CBOE's continued monitoring of foreign currency options trading, in addition to its general surveillance of prearranged trading, should help deter as well as detect any transaction effected for the purpose of increasing a market maker's volume. Accordingly, the Commission believes that increasing the June, July and August 1986 monthly allocations of incentive credits from \$120,000 to \$300,000 for the limited purpose of attracting more market makers to a relatively new product traded mostly by institutional investors should be approved.

Interested persons are invited to submit written data, views and arguments concerning the proposed rule change within 21 days after the date of publication in the Federal Register.

Persons desiring to make written comments should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Reference should be made to File No. SR-CBOE-86-17.

Copies of the submission, all subsequent amendments, all written

^{1 15} U.S.C. 78s(b)(1)(1982).

^{2 17} CFR 240.19b-4 (1985).

^{*} See File No. SR-CBOE-80-7. Securities Exchange Act Release No. 23212 (May 7, 1986), 51 FR 17843.

^{*} Chumming is a broad term that covers a variety of activity, including prearranged trades, wash sales and trade reversals, that is intended to give the appearance of increased trading volume. See Securities and Exchange Commission Report of the Special Study of the Options Markets, H.R. Rep. No. 1FC3, 96th Cong., 1st Sess. (Comm. Print 1978) at 169–72.

statements with respect to the proposed rule change which are filed with the Commission and all written communications relating to the proposed rule change between the Commission and any person, other than those which may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC. Copies of the filing and of any subsequent amendments also will be available for inspection and copying at the principal office of the CBOE.

For the reasons discussed above, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6,* and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of the proposal in the Federal Register in that the concept of a foreign currency options incentive program was previously approved by the Commission and no abuses, to date, have been detected. In addition, the increased limits should encourage continued presence of market makers in currency options during the period that CBOE is seeking Commission approval of further incentives to increase foreign currency options liquidity.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: July 22, 1986. Jonathan G. Katz, Secretary.

[FR Doc. 86-17069 Filed 7-29-86; 8:45 am] BILLING CODE 8010-01-M

[Release No. 34-23464; File No. SR-PHLX-86-20]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc., Order Granting Accelerated Approval of Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15

5 15 U.S.C. 78f (1982)

U.S.C. 78s(b)(1), notice is hereby given that on July 7, 1986, the Philadelphia Stock Exchange, Inc. filed with the Securities and exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Philadelphia Stock Exchange, Inc. ("PHLX" or "Exchange") hereby proposes to extend the applicability of its specialist allocation and evaluation rules (Rules 500 through 506) through December 1, 1986. The Exchange has been applying these rules and intends to continue to apply them until a permanent rule is approved by the Commission.

II. Self-Regulatory Organization's Statement Regarding the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statements of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to extend the Exchange's specialist allocation and evaluation pilot program to enable it to study alternative rule proposal regarding these matters. The Exchange expects that such a proposal regarding permanent rules will be filed with the Commission by the end of this pilot extension period.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Comments on the proposed rule

change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange requests that the proposed rule change be given accelerated effectiveness pursuant to Section 19(b)(2) of the Act to enable it to continue its allocation and evaluation pilot. The pilot was scheduled to terminate on July 1, 1986.

The Commission finds the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, the requirements of Section 6 and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof because of the necessity to allow the Phlx to continue its allocation and evaluation pilot. The Exchange needs the extension to further evaluate the pilot and to develop any changes and amendments to the program which may be appropriate.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments. all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the abovementioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted within 21 days after the date of this publication.

^{* 15} U.S.C. 78s(b)(2) (1982). † 17 CFR 200.30-3(a)(12) (1985)

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

July 24, 1986.

[FR Doc. 86–17070 Filed 7–29–86; 8:45 am]

BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Philadelphia Stock Exchange, Inc.

June 27, 1986.

The above named national security exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following securities:

Inland Steel Industries, Inc. (Holding Company), Common Stock, No Par Value (File No. 7–9105)

USX Corporation, Warrants (File No. 7–9106)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting

system.

Interested persons are invited to submit on or before August 14, 1986, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 86-17067 Filed 7-29-86; 8:45 am]
BILLING CODE 8010-01-M

[Rel. No. IC-15223; File No. (812-6420)]

Dai-Ichi Kangyo Bank (Canada); Foreign Bank Application

July 24, 1986.

Notice is hereby given that Dai-Ichi Kangyo Bank (Canada) ("Applicant"), Commerce Court West, Suite 3740, Toronto M5L IH9 Canada, filed an application on July 10, 1986, for an order of the Commission, pursuant to section 6(c) of the Investment Company Act of 1940 ("Act"), exempting Applicant from all provisions of the Act to enable it to make public offerings of U.S. dollardenominated certificates of deposits ("CD's") and other debt securities in the United States. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below, and to the Act for the text of all applicable provisions thereof.

According to the application, Applicant is a Canadian commercial bank chartered under the Canadian Banks and Banking Law Revision Act 1980 (the "Bank Act"), all of whose outstanding capital stock is owned by The Dai-Ichi Kangyo Bank, Limited ("DKB") a Japanese banking corporation. As of October 31, 1985, Applicant's total assets were approximately \$433 million (Can.) of which approximately \$215 million (Can.) or 50% were loans, and total liabilities were approximately \$414 million (Can.) of which approximately \$370 million (Can.) or 89% were deposits. Applicant represents that it is regulated extensively under Canadian banking laws and that major aspects of its business are subject to such regulation. Furthermore, Applicant is subject to supervision of and examination by the Canadian Inspector General of Banks, the regulatory authority charged with the administration of the Bank Act.

Applicant states that DKB is ranked as the largest commercial bank in the free world (as measured by total assets) as of July 1985, and had assets in excess of \$130 billion as of March 31, 1985. Applicant further states that DKB is regulated extensively by the Japanese Ministry of Finance under Japanese banking laws and the regulations promulgated thereunder. Such regulation includes examinations once very two or three years, and the submission of reports concerning its business or

financial condition.

Applicant states that as a matter of United States law, DKB is a registered bank holding company pursuant to the Bank Holding Company Act of 1956 because of its ownership of Dai-Ichi Kangyo Bank of California, a banking organization chartered under the laws of the State of California, and that DKB is also subject to regulation and reporting requirements under the International Banking Act of 1978. Applicant further states that DKB maintains a branch in New York ("DKB New York"), which is subject to extensive regulation of the

Board of Governors of the Federal Reserve System and the New York State Banking Department, including limitations on banking powers, reserve and reporting requirements and a pledge of assets to cover a fixed percentage of liabilities.

Applicant states that the CD's to be publicly offered by Applicant in the United States will be sold in minimum denominations of \$100,000 (U.S.) through one or more certificate of deposit dealers, will be sold only to institutional and other sophisticated investors, will have original maturities at their respective dates of issuance of not more than five years and will not include any provision for extension, renewal or automatic rollover. It is stated that the proceeds of the inssuance and sale of the CD's will be used by the Applicant for current transactions, including repayment of maturing CD's and payment of current expenses. No part of such proceeds will be made available for the use of DKB and DKB New York. Applicant represents that payment of the principal of, and interest on, the CD's will be unconditionally guaranteed by DKB New York, and that DKB may therefore be regarded as the ultimate obligor with respect thereto. Applicant further represents that the CD's will rank pari passu among themselves and with all other unsubordinated and unsecured indebtedness of Applicant, except for liabilities to the government of Canada or to the government of any province of Canada, and the guarantees in respect thereof will rank pari passu with all other unsecured undebtedness of DKB, except for limited categories of indebtedness given priority by law. Applicant undertakes that, prior to issuance of the CD's, it will obtain appropriate opinions of Japanese and New York counsel to DKB to the effect that: (i) DKB and DKB New York have all necessary power and authority to execute, deliver and perform such guarantee, (ii) the execution, delivery and performance by DKB and DKB New York of such guarantee have been authorized by DKB and (iii) such guarantee constitutes the legal, valid and binding obligation of DKB and DKB New York.

Applicant represents that, prior to issuance, the proposed issuance of CD's and any future offering of debt securities in the United States (together referred to as "Securities") shall have received one of the three highest investment grade ratings from at least one nationally recognized statistical rating organization and Applicant's United States counsel will have certified that such a rating is in effect.

Applicant undertakes that any offering of Securities will be made only pursuant to registration under the Securities Act of 1933, as amended ("1933 Act"), or pursuant to an exemption from the registration requirements of the 1933 Act, and will be done on the basis of disclosure document that are at least as comprehensive as those used in offerings of similar securities in the United States by United States issuers. and which include a memorandum describing Applicant, DKB and DKB New York and containing the most recent publicly available financial statements of DKB and Applicant, audited in accordance with Japanese and Canadian accounting principles, respectively, and their most recent available unaudited interim financial statements. Such memorandum will describe the material differences between generally accepted accounting principles applicable to United States banks and the accounting principles used in the financial statements included in the memorandum. Such memorandum will be updated promptly to reflect material changes in the financial condition of Applicant or DKB. Applicant undertakes to ensure that such disclosure documents will be provided to each offeree of the Securities prior to any sale of Securities to such offeree, but Applicant understands that an inadvertent failure by a dealer to provide an offeree of the Securities with the type of memorandum described above would not be viewed as a violation of its undertaking to furnish such a memorandum.

Applicant also undertakes, in connection with any offering of Securities, that it will appoint an agent for service of process in New York City for any action arising out of the sale of the Securities and consent to jurisdiction of any state or federal court located in New York City in respect of any such action. Applicant states that it will also be subject to suit in any other court in the United States which would have jurisdiction because of the offering of the Securities. Such appointment of an agent and consent to jurisdiction will be irrevocable until all amounts due and to become due in respect of the Securities have been paid. Applicant also undertakes that if it shall make any future offerings of Securities in the United States such Securities shall have the same pari passu status as described above in respect of the CD's, and if such Securities are to be guaranteed by DKB New York, Applicant states that it shall have obtained an opinion of Japanese legal counsel to DKB as to the

enforceability of such guarantee against DKB in accordance with its terms.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than August 19, 1986, at 5:30 p.m., do so by submitting a written request setting forth the nature of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Secretary, Securities and Exchange Commission, Washington, DC 20549. A copy of the request should be served personally or by mail upon Applicant at the address stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. After said date an order disposing of the application will be issued unless the Commission orders a hearing upon request or upon its own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 86-17065 Filed 7-29-86; 8:45 am]

[Release No. 35-24156]

Filings Under the Public Utility Holding Company Act of 1935 ("Act")

July 24, 1986.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by August 18, 1986 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address specified below. Proof of service (by affidavit, or in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing

if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/ or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Energy Investments, Inc. (38-316)

Energy Investments Inc. ("Energy") has filed an application pursuant to section 2(a)(3) of the Act for an order declaring that it will not become "an electric utility company" within the meaning of section 2(a)(3) of the Act as a result of the transactions set forth in the application, which are summarized below.

Energy is a wholly-owned subsidiary of UtiliCorp United, Inc. ("UtiliCorp"), a publicly traded corporation incorporated under the laws of Missouri. Energy intends to be primarily engaged in the business of finance and leasing. UtiliCorp engages primarily directly or through affiliates in the sale and distribution of gas and electricity to retail and wholesale customers. On March 31, 1986, UtiliCorp had assets of over \$720,000,000. Neither UtiliCorp nor any corporation owned or controlled by UtiliCorp is a "holding company" of a "subsidiary company" of a "holding company," as defined in the Act.

El Paso Electric Company ("El Paso"), a corporation organized under the laws of texas, proposes to seel an undivided interest of approximately 15.8 percent in Palo Verde Nuclear Generating Unit No. 2 and a 5.2667 percent undivided interest in certain facilities common to Palo Verde Nuclear Generating Units Nos. 1, 2 and 3 ("Assets") to a Trustee 'Trustee'') as owner trustee under a trust for the benefit of Energy, who will borrow approximately 75 percent of the pruchase price from a funding vehicle. The remainder of the purchase price will be advanced to the Trustee by Energy as an investment in the beneficial ownership of the Assets.

The Trustee will lease the Assets to El Paso under a lease ("Lease") have an initial term of approximately 27 years. El Paso will have the right to renew the Lease and the option to purchase the Assets under certain circumstances. The Lease will be a net lease under which El Paso will be responsible for maintaining, repairing and insuring the Assets and for paying substantially all taxes, assessments and other costs arising from the possession and use thereof.

from the possession and use thereof. Payments received by Energy will not fluctuate with the revenue or income of the Lessee.

The application states that the Federal Energy Regulatory Commission ("FERC") will disclaim jurisdiction over the proposed transactions under section 203 of the Federal Power Act ("FPA") and authorize the issuance of securities and assumption of obligations and liability by El Paso in connection with the proposed transactions under section 204 of the FPA. El Paso, as a public utility, is subject to the FERC's jurisdiction for accounting and other matters. El Paso, as a public utility, is also subject to regulation by the New Mexico Public Service Commisison, which will approve transfer of the assets. According to the application it is expected that both Commissions will approve the Lease.

Neither the Trustee nor Energy will receive any amount based upon the revenue or income of the Lessee. The Trustee will not receive any fee or other payment in connection with the transactions described above, except the Trustee will be entitled to receive reimbursement for a indemification against any costs and expenses incurred

by it in connection therewith.

The applicant represents that it will be a company primarily engaged in one or more businesses other than the business of an electric utility company and that, by reason of the fact that no electric energy will be sold by it as a result of the proposed transaction, it is not necessary in the public interest or for the protection of investors or consumers that it be considered an electric utility company for the purposes of the Act. Energy accordingly requests an order under section 2(a)(3) of the Act declaring that it will not be an electric utility company within the meaning of the act after consummation of the proposed transactions.

The Connecticut Light and Power Company, et al. (70–7275)

The Connecticut Light and Power Company ("CL&P"), Selden Street, Berlin, Connecticut 06037, and Western Massachusetts Electric Company ("WMECO"), 174 Brush Hill Avenue, West Springfield, Massachusetts 01089, subsidiaries ("Companies") of Northeast Utilities, a registered holding company, have filed a declaration with this Commission pursuant to sections 6 and 7 of the Act and Rule 50(a)(5) thereunder.

The proposed transactions relate to the financing of each company's portion of the cost of acquiring, constructing, and installing certain pollution control facilities ("Facilities") at the Millstone nuclear electric generating plant. The Connecticut Development Authority ("Issuer") intends to issue pollution control revenue bonds ("Bonds") in the principal amount of not more than \$80 million for CL&P and \$20 million for

WMECO. The Bonds will be issued under separate CL&P and WMECO Indentures of Trust each between the Issuer and a trustee ("Trustee"). Pursuant to loan agreements between each of CL&P and WMECO and the Issuer, the Issuer will loan the proceeds of the Bonds to CL&P and WMECO. CL&P and WEMCO each will agree to make payments corresponding to the amounts needed to pay the principal of, premium, if any, and interest on the Bonds as they become due. The obligations of each of the Companies to repay its loan will be evidenced by a promissory note. The Bonds will be issued with variable interest rates as floating rate demands bonds and will mature in not more than thirty years. At the option of each of the Companies, the interest rates on the Bonds may be converted to a fixed interest rate upon 45 days' notice. The interest rate will not exceed 20% per annum in any event. Prior to fixing rates, the Bonds may be tendered for payment by holders on seven days' notice. If the Bonds cannot be remarketed, the Trustee may draw upon an irrevocable letter of credit issued by a bank to pay tendering bondholders.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc, 86-17066 Filed 7-29-86; 8:45 am]

SELECTIVE SERVICE SYSTEM

Privacy Act of 1974; Proposed Revision of Systems of Records

AGENCY: Selective Service System.
ACTION: Proposed revision of systems of records.

SUMMARY: The Selective Service System proposed to revise the routine uses in its systems of records SSS-4 and SSS-5.

COMMENT DATE: Comments on these proposed revisions of the systems of records should be submitted in writing or before August 28, 1986, to the General Counsel, Selective Service System, Washington, D.C. 20435. Phone (202) 724–1167.

EFFECTIVE DATE: The revisions in the systems of records will become effective on August 28, 1986, unless the Selective Service System publishes notice to the contrary.

Congress Notice

Notice of these proposed revisions of these systems of records has been filed with the Speaker of the House, the President of the Senate and the Office of Management and Budget, as required by 4 U.S.C. 552a(o).

FOR FURTHER INFORMATION CONTACT: Henry N. Williams, General Counsel, Selective Service System, Washington, D.C. 20435. Phone (202) 724–1167.

SUPPLEMENTARY INFORMATION: The systems of records, SSS-4 and SSS-5 appear at 50 FR 51318, December 16, 1985.

Wilfred L. Ebel,

Acting Director of Selective Service.

July 25, 1986.

Routine uses are revised to read:

SSS-4

Routine Uses of Records Maintained in the System, Including Categories of Users and The Purposes of Such Uses:

Department of Defense—exchange of information concerning registration classification, enlistment, examination and induction of individuals, and for recruiting (prior to April 1, 1982 only on request of the registrant).

Alternative service employers—for exchange of information with employers regarding a registrant who is a conscientious objector for the purpose of placement in and supervision of performace of alternative service in lieu of induction into military service.

Department of Justice—for review and processing of suspected violations of the Military Selective Service Act, or for perjury, and for defense of a civil action arising from administrative processing under such Act.

Federal Bureau of Investigation—for location of an individual when suspected of violation of the Military Selective Service Act.

Immigration and Naturalization Service—to provide information for use in determining an individual's eligibility for re-entry into the United States and United States citizenship.

Department of State—for determination of an alien's eligibility for possible entry into the United States and United States citizenship.

Office of Veterans' Reemployment Rights, United States Department of Labor—to assist veterans in need of information concerning reemployment rights.

Department of Health and Human Services—for locations of parents pursuant to the Child Support Enforcement Act (42 U.S.C. 651 et seq.) and for determining the individual's proper Social Security Account Number when there appers to be a discrepancy.

State and local government agencies-to provide information which may constitute evidence of a violation of State or local law, for law enforcement purposes.

Genral public-Registrant's Name, Selective Service Number, Date of Birth and Classification.

Routine uses are revised to read:

SSS-5

Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of Such Uses:

Department of Defense-for exchange of information concerning registration, classification, enlistment, examination and induction of individuals.

Alternative service employers—for exchange of information with employers regarding a registrant who is a conscientious objector for the purpose of placement in and supervision of performance of alternative service in lieu of induction into military service.

Department of Justice-for review and processing of suspected violation of the Military Selective Service Act or for perjury and for defense of a civil action arising from administrative processing under such Act.

Federal Bureau of Investigation-for location of an individual when suspected of violation of the Military Selective Service Act.

Immigration and Naturalization Service-to provide information for use in determining an individual's eligibility for re-entry into the United States.

Department of State-for determination of an alien's eligibility for possible entry into the United States and United States citizenship.

Office of Veterans' Reemployment Rights, United States Department of Labor-to assist veterans in need for information concerning reemployment rights.

Department of Health and Human Services-for locations of parents pursuant to the Child Support Enforcement Act (42 U.S.C. 651 et seq.) and for determining the individual's proper Social Security Account Number when there appears to be a discrepancy.

State and local government agencies-to provide information which may constitute evidence of a violation of State or local law, for law enforcement purposes.

General Public-Registrant's Name, Selective Service Number, Date of Birth and Classification.

[FR Doc. 86-17094 Filed 7-29-86; 8:45 am] BILLING CODE 8015-01-M

DEPARTMENT OF STATE

* * *

[Public Notice 975]

Property Owned by Diplomatic Missions and Used to House the Staff of Those Missions is Exempt From **General Property Taxes**

The Vienna Convention on Diplomatic Relations exempts the "premises of the mission" from general property taxes which do not represent payment for specific services such as water and sewerage.1 Premises of the mission are defined, generally, as buildings used for mission purposes. Article 1(i). The travauex preparatoire (i.e., legislative history) of these provisions does not address the question of whether "premises" was intended to include staff housing owned by the mission. Until 1980, the United States narrowly construed the Convention tax exemption with regard to housing, to apply only to the Chief of Mission's residence. At that time, in connection with litigation between the German Democratic Republic (hereinafter referred to as GDR) and Arlington County, Virginia, the United States concluded that mission owned staff housing is exempt from real property taxes on the basis of customary international law. See, United States v. Arlington, 669 F.2d 925 (4th Cir. 1982) (Arlington I); United States v. Arlington, 702 F.2d 485 (4th Cir. 1983) (Arlington II).

The Arlington cases resulted from the purchase in 1976 by the GDR of a multiunit apartment building for use exclusively to house personnel attached to the Embassy, and their families. Arlington County, Virginia, attempted to tax the apartment building and in 1978 brought suit to collect unpaid 1977 taxes and to impose a tax lien on the property. The United States did not intervene in that case because, at the time, the Department of State was of the view that such property was taxable. Despite the assertion by the GDR that jurisdiction under the Foreign Sovereign Immunities Act was not available, the District Court heard the case and rendered a judgment in favor of the

county.

The GDR protested the court's verdict. As a result, the United States and the GDR entered into a bilateral agreement in May of 1979 specifically exempting government owned property and the United States filed a separate action to have the Arlington taxation set aside based upon a number of arguments. In that action, the District Court concluded that the property was exempt under the 1979 Agreement from the date of the Agreement, but that the U.S. and GDR were estopped from asserting a tax exemption for the prior period. Both parties appealed. In 1982, the Court of Appeals affirmed that the 1979 Agreement exempted the property, but remanded the question of the tax status of the property during the earlier period. Arlington I, 669 F.2d at 925. On remand, the District Court concluded that the property was exempt for the years prior to 1979 and the County appealed. In 1983, the Court of Appeals upheld the exemption. Arlington II, 702 F.2d at 485.

In the Arlington cases, the Department took the position that mission owned staff housing is exempt from taxation based upon a survey of international practice conducted by the Office of the Legal Adviser. The results of that survey were reflected in a legal opinion furnished in 1980 to the Department of Justice for use in the Arlington litigation. In the opinion, the Department stated that its conclusion that "international law imposes a binding obligation to exempt such property from taxation" was reached on the basis of its study of the sources of international law listed in Article 38(1) of the Statute of the International Court of Justice, "and, in particular, . . . the current virtually uniform practice of states in implementation of the Vienna Convention." As the Department stated in the opinion, "the survey does not always establish with precision whether the exemption is granted because of the receiving state's interpretation of the Vienna Convention or because of its understanding of its obligations under customary international law." The Department took the position that this ambiguity was immaterial since, in either event, the survey reflected a general acknowledgment of a legal obligation to exempt such property on the part of states that are party to the Convention.

In Arlington II, the Court adopted the Department's position.2 Following that

¹ Article 23(1), 23 UST 3227. The Convention entered into force for the United States on December 13, 1972.

² The opinion of the Court suggests that Court found for the United States on a number of grounds, including the 1923 bilateral convention with Germany, the 1979 bilateral agreement with the GDR and international law. While it is clear that the

decision, questions arose regarding the continued empirical validity of the data as well as the wisdom of that position. As a result, the Office of Legal Adviser and the Office of Foreign Missions conducted a more detailed, comprehensive survey of international practice in regard to this issue.

The Department has reviewed its position on the applicability of taxes to property owned by diplomatic missions and used to house the staff of those missions. Based upon the results of the new joint survey, the Department has determined that there is no basis to disturb the conclusion that the Department reached in the Legal Opinion that it provided to the Department of Justice in 1980 in connection with the Arlington litigation. The Department affirms the position that property owned by diplomatic missions used to house the staff of such missions is exempt from general property tax, subject to reciprocal treatment of comparable property owned by the United States abroad. Michael G. Kozak,

Principal Deputy Legal Adviser.
July 21, 1986.

[FR Doc. 86-17025 Filed 7-29-86; 8:45 am] BILLING CODE 4710-08-M

DEPARTMENT OF TRANSPORTATION

[Order 86-7-55, Docket 44196]

Revocation of the Section 401 or 418 Certificates of Air Continental, Inc.; Great Plains Airlines, Ltd.; NAL, Inc.; Orca Air, Inc. D/B/A Chitina Air Service; Sand Point Air Service, Inc.; and Westar International Airways, Inc.

AGENCY: Department of Transportation. **ACTION:** Notice of order to show cause.

SUMMARY: The Department of
Transportation is directing all interested
persons to show cause why it should not
issue an order revoking the section 401
or 418 certificates issued to Air
Continental, Inc.; Great Plains Airlines,
Ltd.; NAL, Inc.; Orca Air, Inc.; d/b/a
Chitina Air Service; Sand Point Air
Service, Inc.; and Westar International
Airways, Inc.

DATE: Persons wishing to file objections should do so no later than August 14, 1986.

ADDRESSES: Responses should be filed in Docket 44196 and addressed to the Documentary Services Division,

Court adopted the United States position on customary international law, it is not entirely clear whether the Court also concluded that the Vienna Convention expressly comprehended staff housing. Department of Transportation, 400 7th Street SW., Room 4107, Washington, DC 20590 and should be served on the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Kathy Lusby, Special Authorities Division, P-47, U.S. Department of

Division, P-47, U.S. Department of Transportation, 400 7th Street SW., Washington, DC 20590, (202) 366-2337.

Dated: July 24, 1986.

Matthew V. Scocozza,

Assistant Secretary for Policy and International Affairs.

[FR Doc. 86-17127 Filed 7-29-86; 8:45 am] BILLING CODE 4910-62-M

[Docket 38883]

Pan American World Airways Employee Protection Program Investigation; Hearing

Notice is hereby given that the hearing in the above-entitled proceeding will commence on August 26, 1986, at 10:00 a.m. (local time), Room 5332, Nassif Building, 400 Seventh Street SW. Washington DC, before the undersigned administrative law judge.

Dated At Washington, DC, July 24, 1985. John M. Vittone, Administrative Law Judge. [FR Doc. 86–171728 Filed 7–29–86; 8:45 am] BILLING CODE 4910–62-M

Federal Highway Administration

Environmental Impact Statement: San Luis Obispo County, CA.

AGENCY: Federal Highway Administration (FHWA), DOT. ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project in San Luis Obispo County, California.

FOR FURTHER INFORMATION CONTACT: Glenn Clinton, District Engineer, Federal Highway Administration, P.O. Box 1915, Sacramento, California 95809, Telephone: (916) 551–1310.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the California Department of Transportation, and the County of San Luis Obispo, will prepare an environmental impact statement on a proposal to replace two wooden bridge structures on South Bay Boulevard about 0.6 miles south of State Highway 1 with a single concrete bridge on new alignment. The proposed project, which is located within the Morro Bay State

Park and adjacent to the Morro Bay Wildlife Refuge, would alleviate the frequent flooding of the existing structures on South Bay Boulevard, one of only two roads providing access to the community of Los Osos/Baywood Park.

Feasible alternatives are limited to replacing the existing structures on essentially the same alignment or doing nothing.

The proposed project will be coordinated with all other responsible agencies. A scoping meeting was held on July 9, 1986 at 9:00 a.m. at the County Government Center, Old County Court House Room 202 (Osos Street entrance) San Luis Obispo, CA 93408.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

Issued on: July 21, 1986.

Lee W. Onstott,

Acting District Engineer Sacramento, California.

[FR Doc. 86-17026 Filed 7-29-86; 8:45 am] BILLING CODE 4910-22-M

Federal Railroad Administration

[BS-Ap-No. 2576]

Burlington Northern Railroad Co.; Public Hearing

The Burlington Northern Railroad
Company has petitioned the Federal
Railroad Administration (FRA) seeking
approval of the proposed discontinuance
of the traffic control signal system from
Mobridge, South Dakota, to Hettinger,
North Dakota, and the automatic block
signal system from Hettinger, North
Dakota, to Terry, Montana. This
proceeding is identified as FRA Block
Signal Application No. 2576.

After examining the carrier's proposal and the available facts, the FRA has determined that a public hearing is necessary before a final decision is made on this proposal.

Accordingly, a public hearing is hereby set for 10 a.m. on September 11, 1986, in the Parmly Billings Library, Third Floor, at 510 N. Broadway in Billings, Montana.

The hearing will be an informal one, and will be conducted in accordance with Rule 25 of the FRA Rules of Practice (49 CFR 211.25), by a representative designated by the FRA.

The hearing will be a nonadversary proceeding and, therefore, there will be no cross-examination of persons presenting statements. The FRA representative will make an opening statement outlining the scope of the hearing. After all initial statements have been completed, those persons who wish to make brief rebuttal statements will be given the opportunity to do so in the same order in which they made their initial statements. Additional procedures, if necessary for the conduct of the hearing, will be announced at the hearing.

Issued in Washington, DC, on July 24, 1986. Phil Olekszyk,

Deputy Associate Administrator for Safety. [FR Doc. 86-17129 Filed 7-29-86; 8:45 am] BILLING CODE 4910-06-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Dated: July 23, 1986.

The Department of Treasury has submitted the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980, P.L. 96–511. Copies of these submissions may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding these information collections should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Room 7221, 1201 Constitution Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545-0441
Form Number: F 6559
Type of Review: Extension
Title: Transmitter Report of Magnetic
Media Filing
OMB Number: 1545-0687
Form Number: IRS Form 990-T

Type of Review: Extension
Title: Exempt Organization Business
Income Tax Return

Clearance Officer: Garrick Shear, (202) 566-6150, Room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224

OMB Reviewer: Robert Neal, (202) 395–6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503

Douglas J. Colley,

Departmental Reports Management Office. [FR Doc. 86–17061 Filed 7–29–86: 8:45 am] BILLING CODE 4810–25-M Comptroller of the Currency

[Document No. 86-16]

Foreign Government Treatment of U.S. Commercial Banking Organizations

AGENCY: Comptroller of the Currency, Treasury.

ACTION: Notice of study and requests for comments.

SUMMARY: As required by the International Banking Act of 1978, the Treasury Department, working with other interested departments and agencies, submitted a "Report to Congress on Foreign Government Treatment of U.S. Commercial Banking Organizations" in September 1979. A limited scope update was made in 1984. A further update is now in process. Public comment is requested on the treatment of U.S. banks in the specific banking markets to be studied.

ADDRESS: Comments should be directed to: Docket No. 86–16 National Treatment Study Update, Communications Division, 3rd Floor, Office of the Comptroller of the Currency, 490 L'Enfant Plaza East, SW., Washington, DC 20219.

DATES: Comments must be delivered on or before August 29, 1986. Comments will be available for inspection and photocopying at the same location.

FOR FURTHER INFORMATION CONTACT:

Alan Herlands, Study Director (Banking), National Treatment Study, Office of the Comptroller of the Currency, (202) 447–1646.

SUPPLEMENTARY INFORMATION: The 1979 Report identified the extent to which U.S. banks were given an opportunity to compete against locally-chartered banks in each of 141 countries. The Report reviewed the legal, regulatory and administrative treatment by foreign governments of U.S. banks, including the right to establish offices, the nature and powers of any banking offices permitted to be established, and the right to own all or part of locally-chartered banks. The policy of providing foreign banks an opportunity to compete on an equal basis with locally-chartered banks is known as "national treatment."

At the request of Senator Jake Garn, Chairman of the Senate Committee on Banking, Housing and Urban Affairs, the Department of the Treasury updated portions of the 1979 Report in 1984. At Chairman Garn's further request, a new report is being prepared concerning the current extent of national treatment of U.S. banks or securities firms.

Preparation of the securities aspects of the new report is the responsibility of the Treasury Department. Preparation of the banking aspects of the new report is the responsibility of the Office of the Comptroller of the Currency. The Comptroller anticipates that national treatment for U.S. banks will be studied with respect to:

- Argentina
- Australia
- · Brazil
- · Canada
- Finland
- IndiaIapan
- · Republic of Korea
- Mexico
- · Norway
- · Philippines
- · Portugal
- · Singapore
- · Spain
- · Sweden
- · Thailand
- · Venezuela
- Taiwan

The Comptroller would welcome the views of U.S. banks or other persons, to be considered in the preparation of the updated report. For each of the banking markets listed above, reponses are invited to the following questions:

1. In what specific respects are U.S. or other foreign banks accorded, or not accorded, an opportunity to compete on an equal basis with locally-owned or locally-chartered banks? Please include, among other subjects, opportunities concerning automatic teller machines.

2. How have these opportunities changed since June 1984? For Argentina and Singapore, how have these opportunities changed since 1979?

3. What major changes have occurred in the financial markets since June 1984 (since 1979 for Argentina and Singapore), and how have those changes affected the extent of national treatment accorded U.S. and other foreign banks?

Dated: July 23, 1986.

Robert L. Clarke,

Comptroller of the Currency.

[FR Doc. 86-17073 Filed 7-29-86; 8:45 am]

BILLING CODE 4810-33-M

UNITED STATES INFORMATION AGENCY

A Grants Program for Private Not-For-Profit Organizations in Support of International Educational and Cultural Activities

The United States Information Agency (USIA) announces a program of selective assistance and limited grant support to non-profit activities of United States institutions and organizations in the private sector. The primary purpose of the program is to enhance the achievement of the Agency's international public diplomacy goals and objectives by stimulating and encouraging increased private sector commitment, activity, and resources. The information collection involved in this solicitation is covered by OMB Clearance Number 3116–0175, entitled "A Grants Program for Private Organizations," expiration date January 31, 1987.

Private sector organizations interested in working cooperatively on the following concept are encouraged to so indicate:

Program on U.S.-Egypt Trade and
Investment: The Office of Private Sector
Programs, Initiative Grants/Bilateral Accords
Division will develop a program for an
Egyptian delegation of public and private
sector officials, tentatively scheduled for late
1986. It will focus on bilateral trade and
investment topics, in particular the key
components of the 1984 Trade and Tariff Act
and the Bilateral Investment Treaty. The
participants will discuss opportunities to
promote US direct investment with

representatives of the Overseas Private
Investment Corporation. They will also meet
with USG officials and potential equity
investors in the Midwest to examine joint
venture options in the agribusiness and
industrial sectors.

Your submission of a letter indicating interest in the above project concept begins the consultative process. This letter should further explain why your organization has the substantive expertise and logistical capability to successfully design, develop and conduct the above project. While not restricted by region, USIA would prefer proposals from U.S. non-profit institutions which demonstrate their ability to conduct the program in Washington, DC, and in either the Midwest or the Southwest.

Emphasis during the preliminary consultative process will be on identifying organizations able to meet the above criteria. Furthermore, USIA is most interested in working with organizations that show promise for innovative and cost-effective programming; and with organizations that have potential for obtaining third-

party private-sector funding in addition to USIA support. Organizations must also demonstrate a potential for designing programs which will have a lasting impact on their participants. In your response, you may also wish to include other pertinent background information. To be eligible for consideration, organizations must postmark their general letter of interest within 20 days of the date of this notice.

This is not a solicitation for grant proposals. After consultation, selected organizations will be invited to prepare proposals for the financial assistance available.

Office of Private Sector Programs, Bureau of Educational and Cultural Affairs, (Attn: Initiative Grants/Bilateral Accords Division), United States Information Agency, 301 4th Street SW., Washington, DC 20547.

Dated: July 21, 1986.

Robert Francis Smith,

Director, Office of Private Sector Programs.

[FR Doc. 86–17027 Filed 7–29–86; 8:45 am]

BILLING CODE 8230-01-M

Sunshine Act Meetings

Federal Register
Vol. 51, No. 146
Wednesday, July 30, 1986

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

1

FEDERAL MARITIME COMMISSION

TIME AND DATE: 11:00 a.m., August 5, 1986.

PLACE: Hearing Room One, 1100 L Street, NW., Washington, DC 20573. STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Petition of the U.S. Atlantic-North Europe and North Europe-U.S. Atlantic Conferences for a Rule Regarding the Term "Shipper" in the Commission's Regulations.

2. Proposed Miscellaneous Amendments to Rules of Practice and Procedure.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, Secretary (202) 523-5725.

Joseph C. Polking,

Secretary.

[FR Doc. 86-17260 Filed 7-28-86; 3:45 pm]

2

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

July 24, 1986.

TIME AND DATE: 10:00 a.m., Thursday, July 31, 1986.

PLACE: Room 600, 1730 K Street, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. Secretary of Labor on behalf of Richard N. Truex v. Consolidation Coal Co., Docket No. WEVA 85-151-D. (Issues include whether the administrative law judge properly found that the operator discriminated against Truex by denying him the right to participate in a section 103(f) post-inspection conference without suffering a loss of pay.)

Any person intending to attend this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 20 CFR 2706.150(a)(3) and 2700.160(e)

CONTACT PERSON FOR MORE INFO: Jean Ellen, 202-653-5629.

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 86-17143 Filed 7-28-86; 10:49 am]

BILLING CODE 6735-01-M

3

FEDERAL RESERVE SYSTEM

(Board of Governors)

TIME AND DATE: 11:00 a.m., Monday, August 4, 1986.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21th Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE

INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: July 25, 1986.

James McAfee,

Associate Secretary of the Board.
[FR Doc. 86–17120 Filed 7–25–86; 4:06 pm]
BILLING CODE 6210–01-M

4

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL ACTION: Notice of meeting to be held pursuant to the Government in the Sunshine Act (5 U.S.C. 552b).

STATUS: Open. The Council will also hold an executive session to discuss civil litigation.

TIME AND DATE: August 6-7, 1986, 9:00

PLACE: Grouse Mountain Lodge, Whitefish, Montana.

MATTERS TO BE CONSIDERED:

Preliminary Council Action on Salmon and Steelhead Research Issue Paper.

2. Preliminary Council Action on Release of Columbia River Basin Fish and Wildlife Program Draft Amendment Document.

3. Staff Presentation and Public Comment on BPA/Council Issue Paper on the Resource Acquisition Provisions of the Northwest Power Act (section 6(c)). (This issue paper is scheduled for distribution in late July. The Council will also take comment at its September 17–18, 1986 meeting.)

4. Public Comment on Draft Workplan for

Western Energy Study.

 Status Report on Reservoir Fisheries Projects in Montana.

6. Council Business.

7. Public Comment.

FOR FURTHER INFORMATION CONTACT:

Ms. Bess Atkins at (503) 222-5161.

Edward Sheets,

Executive Director.

[FR Doc. 86–17142 Filed 7–28–86; 9:15 am] BILLING CODE 0000-00-M

5

POSTAL RATE COMMISSION

TIME AND PLACE: 10:00 a.m., August 6, 1986.

PLACE: Commission Conference Room, 1333 H Street NW., Suite 300, Washington, DC 20268–0001.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Consideration of Fiscal Year 1987 Postal Rate Commission Budget and election of Vice Chairman.

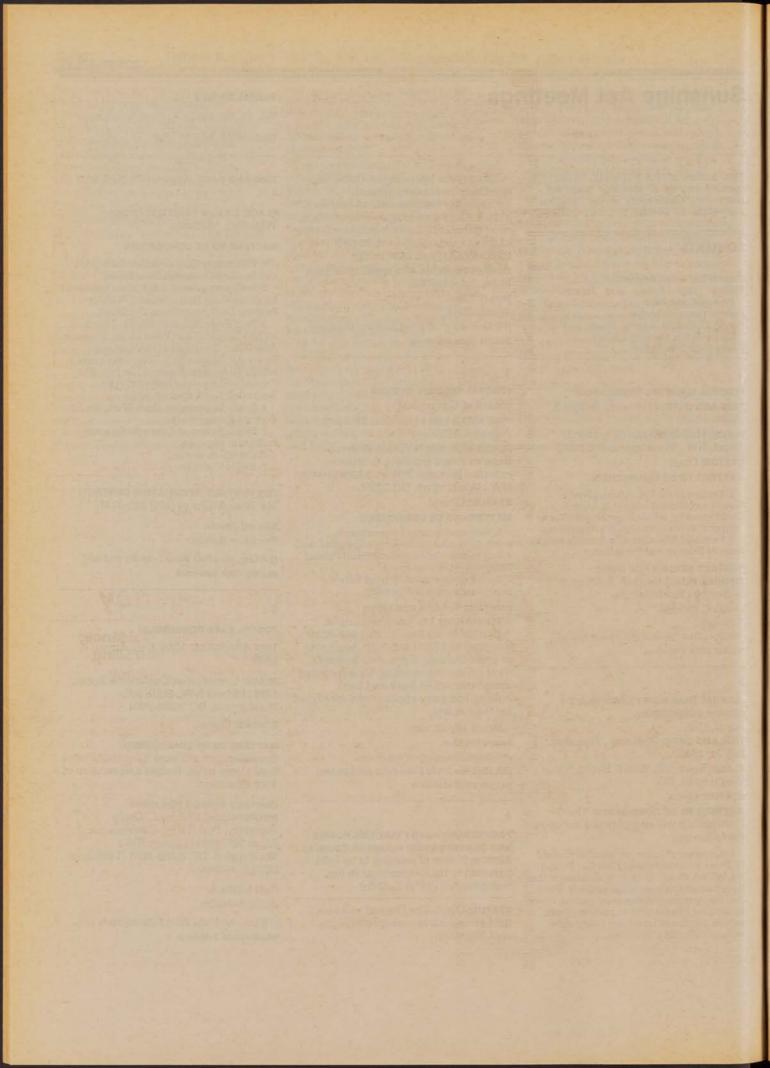
CONTACT PERSON FOR MORE

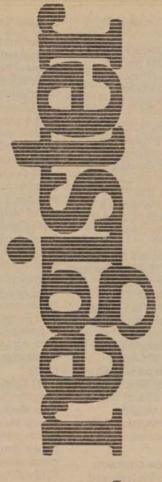
INFORMATION: Charles L. Clapp, Secretary, Postal Rate Commission, Room 300, 1333 H Street NW., Washington, DC 20268–0001, Telephone (202) 789–6840.

Cyril J. Pittack,

Acting Secretary.

[FR Doc. 86-17162 Filed 7-28-86; 10:49 am]
BILLING CODE 7715-01-M





Wednesday July 30, 1986



Environmental Protection Agency

Federal Radiation Protection Guidance; Proposed Alternatives for Controlling Public Exposure to Radiofrequency Radiation; Notice of Proposed Recommendations



ENVIRONMENTAL PROTECTION AGENCY

[2869-2]

Federal Radiation Protection Guidance; Proposed Alternatives for Controlling Public Exposure to Radiofrequency Radiation

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of proposed recommendations, request for written comments on alternatives.

SUMMARY: The Environmental Protection Agency (EPA) is proposing four alternative approaches to limit the public's exposure to radiofrequency (RF) radiation. Three options are regulatory. For frequencies above 3 Megahertz (MHz), Options 1, 2, and 3 would limit whole-body average specific absorption rates (SAR's) to 0.04, to 0.08, and to 0.4 watts per kilogram (W/kg), respectively. Electric field intensity (volts per meter, V/m) and magnetic field intensity (amperes per meter, A/m) would be limited for frequencies below 3 MHz. The limits are 87 V/m and 0.23 A/m, 275 V/m and 0.73 A/m, and 614 V/m and 1.63 A/m for Options 1, 2, and 3, respectively. The fourth option is nonregulatory; information and technical assistance programs would be conducted in lieu of adopting Federal Guidance. Depending on the Agency's final decision, any of the first three options could be recommended to the President as Federal Radiation Protection Guidance for Federal agencies, and whole-body SAR would be directly related to frequency dependent exposure power density values for implementation.

The EPA is considering this action for several reasons. The number and type of RF radiation sources have increased, and the population is continuously exposed to varying degrees; environmental levels of RF radiation and the number of persons exposed to higher levels has grown. Concerns over potential health effects from RF radiation have also heightened. Effects occur in test animals exposed at RF radiation intensities found in the environment. The need for Federal Guidance for RF radiation has been expressed to the Agency by Federal and other governmental bodies, by industry, and by the public.

DATES: The Agency is seeking written comments on this Notice, and all written comments will be carefully considered in preparing final recommendations to the President. Written comments must be received on or before October 28, 1986.

ADDRESSES: Written comments should be submitted to the Central Docket Section (LE-131), U.S. Environmental Protection Agency, Attn.: Docket Number A-81-43, Washington, DC 20460.

Docket No. A-81-43, containing material relevant to this proposal, is located in the West Tower Lobby, Gallery 1, Central Docket Section, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC. The Docket may be inspected between 8 A.M. and 4 P.M. on weekdays, except holidays. A reasonable fee may be charged for copying.

Single copies of background reports on environmental levels of RF radiation, biological effects, and the potential costs of Federal Guidance for RF radiation may be requested in writing from the Program Management Office (ANR-458), U.S. Environmental Protection Agency, Washington, DC 20460, or by calling (202) 475-8388.

A copy of each of the reports is also available for inspection at EPA's Central Docket Section (address above) and at the library in each of the 10 EPA Regional Offices. See SUPPLEMENTARY INFORMATION for the locations of the 10 regional libraries.

FOR FURTHER INFORMATION CONTACT: David E. Janes, Director, Analysis and Support Division (ANR-461), Office of Radiation Programs, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 475-9626.

SUPPLEMENTARY INFORMATION:

I. Statutory Authority

Federal radiation protection guides are developed by the Environmental Protection Agency (EPA) under the Federal Radiation Council Authority (Pub. L. 86-373), transferred to EPA by Reorganization Plan No. 3 of 1970, as codified at 42 U.S.C. 2021(h). The Administrator of the Environmental Protection Agency is charged to "advise the President with respect to radiation matters, directly or indirectly affecting health, including Guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States." Upon Presidential approval of EPA recommendations, the pertinent Federal agencies are responsible for implementing Guidance. The Agency's authorities for Federal Radiation Guidance also require the Administrator to consult with the National Council on Radiation Protection and Measurements (NCRP) and other expert bodies.

II. Basic Terms Used in This Notice

Various technical terms are used throughout this Notice and are defined below. The reader is also referred to other reference documents (1, 2) for description of technical terms.

(a) Consumer Electronic Product—For the purpose of this Notice, any consumer product that emits, or has the potential to emit, radiofrequency radiation, e.g., a microwave oven.

(b) Continuous Exposure—Exposure equal to or greater than 6 continuous minutes. Exposure less than 6 minutes is called short-term.

(c) Electric Field Strength (E)—The force exerted on a stationary unit of positive charge at a point in an electric field. Electric field strength may be expressed in volts per meter (V/m).

(d) Energy Density—The instantaneous power density integrated over its duration. Energy density may be expressed in units of power density-time, e.g., microwatt-minute per square centimeter or Watt-second per square meter.

(e) Equivalent Plane-Wave Power Density (S)—The power density derived from electric (E) or magnetic (H) field strengths with the assumption that the relationship between power density and field strength is the same as that for plane waves in free space. In free space, E/H=377 ohms. [See also the definition for power density.]

(f) Exposure—Exposure occurs whenever and wherever a member of the public is subjected to external electric, magnetic, or electromagnetic fields, and/or is subjected to low frequency electric shock when making contact with an electrically grounded object. [See also the definitions for power density and specific absorption rate.]

(g) Far Field Region—A region in the field of an antenna, located far enough from the antenna so that the electric and magnetic fields have essentially a planewave character, i.e., locally very uniform distributions of electric field strength and magnetic field strength in planes transverse to the direction of propagation. For large antennas especially, the far field region is also called the Fraunhofer region.

(h) Hertz (Hz)—A unit for expressing frequency (f) in units of cycles per second, i.e., one Hz is defined as one cycle per second. For RF radiation in air, the frequency of electromagnetic waves is related to wavelength by the relationship f=c/w avelength where c, the velocity of radiowaves, is 3×10^8 meters/second, and wavelength is in units of meters. This relationship is

illustrated below where the frequency may be expressed in multiplicative units of Hz as shown.

Frequency	Wavelength (meters)
10 kilohertz (kHz) = 10,000 Hz	30,000 3,000 300 300
1 megahertz (MHz) = 1000 kHz	
100 MHz I gigahertz (GHz) = 1000 MHz	0.3
10 GHz	0.03

(i) Magnetic Field Strength (H)—The force on a hypothetical stationary unit magnetic north pole at a point in a magnetic field. Magnetic field strength may be expressed in amperes per meter (A/m) or milliamperes per meter (mA/m).

(j) Mixed Frequency Fields—Exposure fields which consist of more than one RF

radiation frequency.

(k) Near-Field Region—A region in the field of an antenna, located near the antenna, in which the electric and magnetic fields do not have essentially a plane-wave character but vary considerably from point to point. The near-field region has a different size and geometry (shape) for large and small antennas. The near-field region is further subdivided into the reactive near-field region, which is closest to the antenna and contains most or nearly all of the stored energy associated with the field of the antenna, and the radiating near-field region.

(1) Plane Wave—An electromagnetic wave with parallel or nearly parallel planar surfaces of constant phase.

(m) Power Density (S)-The magnitude of the electromagnetic energy flux density at a point in space, expressed in power per unit area such as watts per square meter, milliwatts per square centimeter, or microwatts per square centimeter. For plane waves, E. H, and direction of propagation are mutually orthogonal (perpendicular). E2 and H2 are simply related to power density, i.e., $S = E^2/3770$ or S = 37.7 H² in units of milliwatts per square centimeter where E = electric field strength (V/m) and H=magnetic field strength (A/m). E2 and H2 are the actual quantities measured by many survey meters even though the instrument is calibrated to indicate power density units. The general relationship between power density and SAR is discussed in Section

(n) Product Performance Standard— Refers to a standard which limits RF radiation emitted from a specific product under specified operating conditions; these standards establish tests to be performed by a manufacturer during or immediately after product assembly. The specific maximum allowable emission values are set so as to provide appropriate protection of the public during normal operation of the product. Such values are not the same as "exposure limits," as considered by this Notice. Product performance standards are promulgated under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) and are administered by the Food and Drug Administration (FDA).

(o) Public-The term "public" in this Notice means all persons except: (a) workers, to the extent they are occupationally exposed to RF fields produced by activities of their employer at the place of employment whether or not their duties directly involve RF radiation, (b) patients, to the extent they are exposed due to prescribed medical treatment or procedures using RF fields, and (c) persons, to the extent they are exposed as a result of the use of consumer electronic products (see definition (m), Product Performance Standard). The intent is to consider these people as members of the public except when they are exposed from

occupational activities, medical procedures, and/or consumer electronic products, respectively.

(p) Pulse Modulated Field—An electromagnetic field which is caused by the modulation of a carrier by a series of

pulses.

(q) Radiofrequency (RF) Radiation— Defined as electromagnetic fields within the frequency range of 10 kHz to 100 GHz in these recommendations.

(r) Root-Mean-Square (RMS)—Certain electrical effects are proportional to the square root of the mean value of the square of a periodic function (over one period). This value is known as the effective value or the root-mean-square (RMS) value since it is derived by first squaring the function, determining the mean value of this squared value, and extracting the square root of the mean value to determine the end result.

(s) Short-Term Exposure—Exposure for less than 6 continuous minutes.

(t) Specific Absorption Rate (SAR)— The time derivative of the incremental energy (dW) absorbed by (dissipated in) an incremental mass (dm) contained in a volume element (dV) of a given density

$$SAR = \frac{d}{dt} \left(\frac{dW}{dm} \right) = \frac{1}{D} \frac{d}{dt} \left(\frac{dW}{dV} \right)$$

The specific absorption rate is expressed in units of watts per kilogram (W/kg). Conventionally, the SAR in tissue is expressed as:

$$SAR = \frac{C_t E^2}{D}$$

where

Ct-tissue conductivity at the irradiation frequency (mhos per meter),

E_t=RMS electric field strength in the tissue (volts per meter), and

D=tissue density (kilograms per cubic meter).

Note that E_t is not the same as the external electric field (E) which is specified by the proposed limits discussed in this Notice.

The general relationship between exposure, measured as power density, and SAR is discussed in Section IV.B.

III. Background

The Concern

Manmade RF radiation is part of modern society. Applications are found in communications, transportation, defense, industry, consumer products. security, and medicine. Essentially everyone in the United States is continuously exposed to low levels of RF radiation, and some people who live or work near powerful sources are exposed to higher levels. RF radiation sources have steadily increased in number, and their uses have diversified so that a general increase in exposure levels in the environment has occurred. Various effects occur in experimental animals exposed to intensities which are found in the general environment. The increase in sources coupled with a better understanding of biological effects has heightened concerns about potential adverse effects on public health from exposure to RF radiation.

Existing Standards

There are no Federal standards or guidelines for controlling exposure of the public to RF radiation in the environment. As a result, in 1982 the Federal Communications Commission (FCC) proposed the adoption of interim standards for public exposure to RF radiation until Federal guides were adopted, or standards were promulgated by EPA (3). The FCC recently decided to use the 1982 voluntary American

National Standards Institute (ANSI) standard (discussed below) in processing license applications and facility modifications under its National Environmental Policy Act (NEPA) responsibilities (4). The Food and Drug Administration (FDA) has established a product performance standard for microwave ovens to limit leakage of radiation (21 CFR 1010.10); this is a performance standard rather than an exposure standard.

The lack of a Federal public exposure standard has led to diverse regulatory activity by State and local governments. The city of Portland (5) and Multnomah County (6) in Oregon have enacted amendments to zoning ordinances to control construction of new facilities. The town of Onondaga, New York (7) has issued a moratorium on construction of new RF radiation transmitting systems until Federal public exposure guidance is available. The City of New York has had a proposal to control population exposures under consideration for a number of years (8). Massachusetts (9), Texas (10) and New Jersey (11) have enacted statutes to limit exposure. In Connecticut, Public Act No. 84-383 (effective June 8, 1984) directs the Connecticut Commissioner of Environmental Protection to adopt the 1982 American National Standards Institute voluntary standard.

The American National Standards Institute (ANSI) developed a voluntary standard for occupational exposure in 1966 (12) which was reaffirmed with minor changes in 1974 (13). The ANSI is a private, non-profit organization that, among other things, coordinates the development of voluntary national standards, primarily for technical, industrial, and manufacturing practices. ANSI standards are intended as guides to aid manufacturers, consumers, and the public. The Occupational Health and Safety Administration (OSHA) adopted the 1966 ANSI standard for occupational exposure in 1971 (14), permitting an exposure of up to 10 milliwatts per square centimeter for frequencies between 10 MHz and 100 GHz. The OSHA standard was determined to be merely advisory in 1976 (15) and was implemented by OSHA under the General Duty Clause of the Occupational Safety and Health Act (16) until March 1982 at which time OSHA proposed to revoke its standard (47 FR 23477). In February 1984, OSHA determined to retain its standard because it provided useful advice for employers (49 FR 5318).

The ANSI revised its voluntary standard in 1982. This standard is now frequency dependent with more stringent levels of exposure in certain frequency ranges. For example, a maximum exposure level of 1 milliwatt per square centimeter is specified for frequencies between 30 and 300 MHz (17).

Occupational exposure standards in most Western countries range from 1 to 10 milliwatts per square centimeter. These levels limit the amount of heat that is generated when RF radiation is absorbed in human tissue. Eastern European countries, e.g., USSR, Poland, and Czechoslovakia, have lower exposure standards for most occupational situations. In the USSR, for example, the occupational standard is 0.025 milliwatts per square centimeter (25 microwatts per square centimeter) for frequencies above 300 MHz (18). These Eastern European standards are largely based on behavioral and clinical studies that, for the most part, have not been repeated or replicated in other countries because reports on these studies generally lack sufficient description of needed technical details.

The National Council on Radiation Protection and Measurements (NCRP) recently recommended RF exposure criteria for the public (19). A draft proposal was first reported at the 1984 Annual Meeting of the NCRP on April 5, 1984 in Washington, DC. The NCRP is a nonprofit corporation chartered by Congress that collects, analyzes, develops, and disseminates information and recommendations about radiation protection and radiation measurements, quantities, and units. The International Radiation Protection Association (IRPA) published interim guidelines for exposure to radiofrequency radiation in April 1984 (20). The IRPA is an international scientific union of various national health physics and radiation protection associations. Although the limits recommended by NCRP and IRPA are generally similar to the 1982 ANSI standard in derivation and form, they are five times more stringent for exposure of the public. In addition, the Applied Physics Laboratory of Johns Hopkins University, based on results of research there, established an exposure limit of 100 microwatts per square centimeter for frequencies between 30 MHz and 100 GHz for all employees regardless of whether their jobs directly involved exposure to RF radiation (21).

The exposure levels recommended by the ANSI, IRPA, NCRP, Massachusetts, Multnomah County, Portland, New Jersey, and Connecticut are all based on the concept that whole-body average specific absorption rates (SAR's) should be the same for all frequencies above 3 MHz. This approach requires different exposure levels at different frequencies. Also, the guidelines developed to date are based largely on the same assessment criterion used by ANSI, i.e., whole-body average SAR's greater than 4 W/kg cause behavioral effects in irradiated animals. Behavioral disruption was selected by ANSI as the most reliable indicator of a potentially harmful health effect although other harmful effects including lethality occur around 4 W/kg and various other biological effects have also been experimentally determined or theoretically predicted to occur at lower SAR values. The ANSI then applied a safety factor of 10 to specify a permissible whole-body average SAR of 0.4 W/kg which provided the basis for limiting power densities for human exposures (17). The other standards are lower than the ANSI standard primarily because a larger margin of safety was determined to be necessary for the general population; the safety factors applied to derive exposure limits range from 50 to 100.

One important reason for the different determinations of appropriate margins of safety is the judgment on whether a distinction should be made between occupational and public exposures. Previous ANSI guides have been widely interpreted as occupational standards, but ANSI intended its 1982 guide to apply to both occupational and nonoccupational exposures and stated its guides were offered as upper limits of exposure, particularly for the population at large (17). The use of a single standard for both occupational and public exposures is a departure from traditional practices in public health protective regulations which usually differentiate between occupational and general populations. Environmental health criteria for RF radiation published by the World Health Organization (WHO), used as the scientific basis for the IRPA guidelines. state that "exposure of the general population should be kept as low as readily achievable and exposure limits should generally be lower than those for occupational exposure." (22) It is also a practice of the NCRP to differentiate between occupational and general populations (23). Among the reasons cited by groups such as IRPA or NCRP for more stringent general population exposure standards are that the general public comprises individuals of all ages, different health status, and varying susceptibilities and there is the possibility of continuous and lifelong exposure.

Related Activities by EPA

An Advance Notice of Proposed Recommendations (ANPR) published in the Federal Register on December 23. 1982 (47 FR 57338), announced the Agency's intent to develop guidance for Federal agencies to use to limit exposure of the public to RF radiation (24). The ANPR provided background information relevant to the development of Federal guidance. Comments were received from the public in response to the ANPR. These comments supported the development of Federal Exposure Guidance for RF Radiation and, in some cases, recommended specific exposure limits. These comments are available for public examination in Docket Number A-81-43 in the Central Docket Section of the EPA (see ADDRESSES).

An Interagency Work Group was established to provide information to EPA on issues of concern to Federal agencies and to comment on drafts of this Notice. Though the draft reviewed by the Work Group consisted of only Option 1, most of the comments received are pertinent to all options. This group is comprised of sixteen Federal agencies and three governmental advisory bodies. The Interagency Work Group includes the Federal Communications Commission, Central Intelligence Agency, Federal Aviation Administration (FAA) in the Department of Transportation, Occupational Safety and Health Administration (Department of Labor). National Bureau of Standards (Department of Commerce), National Science Foundation, National Aeronautics and Space Administration, Department of Energy, Food and Drug Administration (Department of Health and Human Services), Department of State, Department of Agriculture, Voice of America (United States Information Agency), Department of Defense (DOD), Coast Guard (Department of Transportation), Veterans Administration, National Telecommunications and Information Administration (Department of Commerce), National Academy of Sciences, National Council on Radiation Protection and Measurements, and the Conference of Radiation Control Program Directors.

The Environmental Protection Agency operates an environmental monitoring and assessment program on RF radiation and has supported a biological effects research program in this area. These activities have enabled the Agency to develop the information necessary for this Notice. Three background reports have been prepared and are largely based on results from the Agency's research and

environmental assessment programs. Biological Effects of Radiofrequency Radiation provides an in-depth critical review of the biological effects literature (25). The Radiofrequency Radiation Environment: Environmental Exposure Levels and RF Radiation Emitting Sources evaluates sources and levels of RF radiation in the environment (26). An Engineering Assessment of the Potential Impact of Federal Radiation Guidance on the AM, FM, and TV Broadcast Services analyzes the potential impact of various proposed control levels on affected RF sources and users of the electromagnetic spectrum (27). Another report, An Estimate of the Potential Costs of Guidelines Limiting Public Exposure to Radiation from Broadcast Sources, details economic impact analyses (28). Information on how to obtain these reports is given in Section IX of this Notice.

Under the aegis of the Agency's Science Advisory Board (SAB), a Subcommittee on the Biological Effects of RF Radiation was established to evaluate the scientific adequacy and technical merit of drafts of the report Biological Effects of Radiofrequency Radiation. The final report was revised in accordance with the comments of this Subcommittee. Subcommittee reports and meeting transcripts are also available for public review in EPA Docket No. A-81-43 (see ADDRESSES).

Issues Addressed

EPA has received numerous comments on the ANPR and a published draft of Biological Effects of Radiofrequency Radiation (29).
Comments have also come from the Interagency Work Group. Overall, the comments expressed a need for the development by EPA of Radiation Protection Guidance for limiting exposure of the public to RF radiation. Analysis of the comments identified at least seven major issues of concern.

1. Future efforts to develop and carry out implementation programs will require resources to acquire and develop personnel and capabilities which most Federal agencies do not now have. Several agencies, including the FCC and FAA, have indicated they may request assistance from EPA. If Guidance is established, the Administrator of EPA will establish a capability to develop and evaluate the measurement techniques and systems needed to allow EPA to exercise oversight responsibilities to assist Federal agencies in developing implementation and compliance programs.

Many Federal agencies expressed concern that it may be difficult to distinguish between public exposure and occupational exposure when implementing Guidance in Federal facilities. Is an individual to be classified as a "member of the public" or as a "worker": (a) If duties when working at a facility do not directly involve RF radiation, but exposure to levels exceeding the Guidance limits occurs, or (b) when visiting a facility where exposure levels generally exceed environmental exposure limits? To clarify this situation in part, we propose to exclude all persons who are occupationally exposed to RF fields produced by activities of their employer at the place of employment whether or not their duties directly involve RF radiation. But, EPA is soliciting comment on this matter and is especially interested in how to treat exposures to members of the general public who may visit Federal facilities.

- 3. The Food and Drug Administration (FDA) did not want any EPA Guidance to conflict with their responsibilities for developing product performance standards. EPA proposes, therefore, to exclude from consideration those exposures of the public resulting from electronic consumer products. Certain electronic consumer products may cause exposures that exceed the various limits discussed in this Notice, but any such exposures might be more readily controlled by product performance standards.
- 4. Several Federal agencies were concerned that EPA Guidance for general population exposure will mistakenly be viewed by their employees as an occupational exposure standard. Notwithstanding these concerns, EPA believes the target population is explicitly and sufficiently delineated in this proposal.
- 5. Some Federal agencies are concerned that compliance with general population exposure guidance will affect some Federal operations involving RF sources. Even for the most stringent control levels under consideration, EPA analyses indicate relatively minor impact on Federal operations; unofficial estimates by certain agencies are in disagreement. However, one major DOD organization suggested its analyses were consistent with EPA's assessment of little impact. But, the extent of impact is apparently related to issue 2, above, i.e, whether employees not directly working with RF sources should be classified as occupationally exposed. The EPA asked the Federal agencies to identify sites they consider might present potential compliance problems. The EPA hopes to measure exposure levels at some of these sites to help

provide information which may be useful in resolving the questions raised.

6. The Report on Biological Effects and the composition of the SAB subcommittee that reviewed the report were criticized (30). Effects due to modulated RF fields and at frequencies below 10 kHz were of particular concern. This proposal makes no special provision for modulated RF fields because the scientific data on how such fields interact with biological systems is not considered to be sufficiently developed to permit an assessment of the potential human health consequences of exposure to such fields. Modulation is an important issue in need of more research, and if more adequate information becomes available modulation may be addressed in the future. Additionally, EPA intends to treat exposures to fields at frequencies less than 10 kHz as a separate subject for possible future Guidance.

7. A need for Federal Guidance to control exposure of the public to RF radiation was expressed to EPA by local and State governments, other Federal regulatory agencies, industrial groups, and private citizens. For example, the National Telecommunications and Information Administration (NTIA) has urged EPA to "devote all resources necessary to support its research and efforts to promulgate these guidelines as soon as possible" (31). Two major concerns have been identified: (1) a concern for the potential public health consequences of increasing and continuous exposure to RF radiation in the environment, and (2) a desire that local and State standards should be based on Federal Guidance rather than many diverse standards developed

individually.

The need for Federal exposure guidance to protect public health has emerged as an important issue as RF radiation sources, uses, and, thus, exposures have increased and as our understanding of the biological effects from RF radiation exposure has improved. Essentially everyone in the United States is continuously exposed to very low levels of RF radiation. People who live or work near powerful sources are exposed to higher levels. It is now known that various effects occur in experimental animals exposed to certain intensities that are found in the general environment and to which people are exposed. In addition, levels of RF radiation in the environment are expected to continue to increase with continued growth in telecommunications and other sources. From a public health perspective, therefore, any establishment of Federal exposure

guidance could be viewed as both a corrective and preventive action to (1) correct existing exposure problems by reducing potentially harmful levels and eliminating easily avoidable exposures to levels believed to be safe and (2) assure that environmental levels of RF radiation in the future do not increase above acceptable levels.

Federal Guidance has become important also because its absence has led to varying State and local government actions affecting the construction and use of new transmitting facilities, particularly in the telecommunications industry, as well as to enactment of several different public exposure standards. Segments of the telecommunications industry have urged establishment and adoption of a uniform Federal exposure standard to forestall what is viewed as the disruptive and costly impact of diverse local regulatory activity on the development of telecommunications facilities (32-36).

IV. Basis for This Proposal

A. RF Radiation in the Environment

EPA has conducted monitoring and measurement programs and extensively analyzed sources and levels of RF radiation in the environment. The results of these studies, summarized below, are discussed in detail in the technical report, The Radiofrequency Radiation Environment: Environmental Exposure Levels and Radiofrequency Radiation Emitting Sources, which has been placed in the docket. Typical sources of RF radiation include AM and FM radio and television broadcast stations, radars, satellite communication and microwave relay systems, land mobile radio, and amateur radio. The number, types, and uses of RF radiation sources have rapidly expanded.

Extensive environmental RF measurements made by EPA have shown that the sources most likely to produce the highest population exposure levels are domestic broadcast stations with frequencies between 535 kHz and 806 MHz. Some of the most intense public exposures result from emissions within the FM radio broadcast band at frequencies between 88 and 108 MHz. It is significant that this frequency band falls within the range for resonant absorption (a concept discussed in the next section on dosimetry) for humans resulting in maximal rates of energy

absorption by the body.

Levels of exposure are determined by how close people are to a RF source, i.e., exposure intensity generally decreases as the distance from a radiating source increases. Exposure may result from one source or many sources. Most people,

particularly in urban areas, receive their exposure from the superposition of RF fields emitted from many sources that operate at different frequencies.

Data in Tables 1 and 2 are presented in terms of power density (microwatts per square centimeter). Power density can be related to the rate at which energy is absorbed. For example, for FM and VHF frequencies, 1,000 microwatts per square centimeter corresponds to about 0.4 W/kg. Dosimetric relationships are described in detail in the next section and in Chapter 3 of reference 25.

Based upon analyses of extensive measurements in 15 metropolitan areas (see Table 1), EPA estimates that the typical median exposure in urban areas is 5 nanowatts per square centimeter and that typical exposures for most of the population, over 99 percent, is less than 1 microwatt per square centimeter. It is important to note that these "typical" population exposure estimates represent exposures that occur far from RF sources and exclude population exposures for individuals living or working close to the RF sources. Also, these exposures do not take into account population mobility, exposures at heights of greater than six meters above ground, building attenuation, and periods when the sources are not transmitting.

In contrast to these "typical" exposures, higher values than those shown in Table 1 can occur at locations near to the antennas of broadcast stations and other sources. Some representative exposures obtained from EPA studies near antennas are summarized in Table 2. From present information it is not possible to estimate the number of people continuously or intermittently exposed to these higher levels. However, the number of sources capable of producing various levels were estimated in analyzing the costs of different control levels, and the results are summarized in Section VII. B.

In summary, if an individual's exposure is predominantly due to a nearby source(s), it can be significantly higher than exposures associated with the multisource environments as described. The EPA has determined that approximately one percent of the U.S. population is exposed to RF fields from VHF broadcasting with intensities greater than one microwatt per square centimeter (37). Exposures due to nearby sources in publicly accessible areas may reach maximum values in the 1-10 milliwatts per square centimeter range or higher, but the number of people exposed to these levels is not yet well characterized.

B. Electromagnetic Field Interactions and Dosimetry

RF radiation can be absorbed. reflected, or transmitted by the body. The amount of radiation that is absorbed is what is important when determining whether given levels of RF radiation exposure are harmful. It is, thus, necessary to be able to relate the intensity (power density) of exposure to the actual rate at which energy can be absorbed by an individual. The rate of energy absorption is called "specific absorption rate" or SAR and is given in units of watts per kilogram of body mass (W/kg). Except under controlled experimental conditions, SAR cannot be directly determined by measurements on humans, but it is proportional to the intensity of incident electromagnetic fields, or power density, which can be measured.

TABLE 1.—ESTIMATED POPULATION EXPOSURE FOR 15 U.S. CITIES IN MICROWATTS PER SQUARE CENTIMETER

[54-806 MHz]

City	Median exposure	Percent exposed to less than 1 microwatt/ cm²
Boston	0.018	98.50
Atlanta		99.20
Miami	0.0070	98.20
Philadelphia	0.0070	99.87
New York	0.0022	99.60
Chicago	0.0020	99.60
Washington	0.009	97.20
Las Vegas		99.10
San Diego	0.010	99.85
Portland	0.020	99.70
Houston	0.011	99.99
Los Angeles	0.0048	99.90
Denver	0.0074	99.85
Seattle	0.0071	99.81
San Francisco	0.002	97.66
All Cities	0.0048	99.44

TABLE 2.—RANGE OF MEASUREMENTS LOCATED NEAR BROADCAST ANTENNAS¹

Power Density microwatts per square centimeter		
Tall Buildings: FM, TVAM		Electric Fields. Magnetic Fields.
Ground Level: FM, TVAM	10-7,000 106-23,900 (20-300 V/m) 1,510-3.05×10° (0.2-9 A/m)	Electric Fields. Magnetic Fields.

Abstracted from various EPA measurement survey reports. Measurements were made very near antennas, usually within 200 feet or fess. For AM frequencies, the electric and magnetic field strength equivalents of the power density are given for ease in comparison to the field strengths given in the various options.

The SAR is the rate of energy absorption at any point within an

absorbing body and will vary from point to point within the body. The maximum value of the SAR is called the peak SAR. The conventional use of SAR is in reference to the energy absorption rate of the body as a whole; called "wholebody average SAR" indicating that the SAR has been averaged over the entire body mass. It is this whole-body average SAR that is most commonly specified in studies of the biological effects of RF radiation. The value of the whole-body average SAR for man or laboratory animals depends on the interaction of several factors such as the size, shape, electrical properties, and position of the body in relation to the polarization and frequency of the RF radiation field (for example, AM versus FM radio waves). These various factors determine the frequency at which the whole-body average SAR of an absorbing object reaches its maximum value, the so called resonant frequency. The resonant frequency for humans lies in the range of 30-300 MHz. For example, in this range, which includes the frequencies for FM radio and VHF-TV broadcasts, exposure at an incident power density of 1,000 microwatts per square centimeter can result in a wholebody average SAR of approximately 0.4 W/kg. Dosimetric relationships are described in detail in Chapter 3 of reference 25.

The SAR given in biological effects research is commonly averaged over time as well as averaged over the body mass of test animals. In the following discussion of biological effects the terminology "whole-body average SAR" means that the SAR is averaged over time unless noted otherwise.

To summarize, in contrast to power density, SAR's better describe how energy is absorbed in the body, are more reliable predictors of biological effects, and permit comparison of one health effects study to another. Specific absorption rates instead of power densities are, thus, used below to discuss health effects.

C. Health Effects of Radiofrequency Radiation

1. The Relationship Between Effects and Specific Absorption Rates (SAR's)

The scientific literature on the biological effects of RF radiation has been critically reviewed by the Agency in Biological Effects of Radiofrequency Radiation, and the major findings from the report are excerpted and given below (25). It should be noted that epidemiological data are currently very limited and, thus, are not useful for deriving environmental exposure limits. Great reliance, therefore, must be placed

on experiments with animals to derive environmental exposure limits. The results discussed below are obtained from animal experiments unless specifically noted to be drawn from human data. The reader is referred to Biological Effects of Radiofrequency Radiation for citations (25).

(a) High level RF radiation is a source of thermal energy (as seen with, for example, microwave ovens) that carries all of the known implications of heating for biological systems. At a given incident field strength, maximal heating occurs at the resonant frequency (D'Andrea et al. 1977). In general, the data are consistent with the hypothesis that the SAR required to raise the body temperature of laboratory animals decreases as body mass increases; that is, a lower SAR is needed to produce a given significant increase in the temperature of a large laboratory animal than is required to achieve the same temperature rise in a small animal.

(b) Relatively short duration wholebody exposure of laboratory animals at whole-body average SAR values greater than 30 W/kg can be lethal; lethal SAR levels vary with species and exposure conditions. [Additional information on lethality is given further in this Section.]

(c) Brief exposures (less than 5 minutes) of the whole body to high intensity RF radiation may result in significant biological damage, e.g., birth defects, increased embryonic and fetal resorptions, lowered birth weights, and reduced survival of infant animals irradiated both before and after birth. Localized exposure to very high intensity RF radiation can result in burns; for example, facial burns on monkeys have been reported at 115 W/kg.

(d) A single short exposure of the eye to high-intensity RF radiation, if applied for sufficient time, is cataractogenic in some experimental animals. In the rabbit, the animal most often used in ocular studies, the cataractogenic threshold for a 100-minute exposure is 150 milliwatts per square centimeter (138 W/kg peak SAR in the lens). The cataractogenic potential of microwave radiation varies with frequency; the most effective frequencies for producing cataracts in the rabbit eye appear to be in the 1 to 10 GHz range. Cataracts have not been produced in primates acutely exposed to RF radiation under conditions that caused cataracts in lower mammals. This is attributed to the different facial structure in primates that causes a different pattern of absorbed energy in the eye. No cataracts have been reported in rabbits after wholebody, far-field RF radiation exposures,

at SAR's of 42 W/kg for 15 minutes. No data at present support a conclusion that low-level, chronic exposure to microwave radiation induces cataracts in human beings, although some studies have associated ocular-lens defects with microwave radiation exposure.

(e) In most of the animal studies that report a biological effect of RF radiation, exposures occurred at ambient temperatures of 20-25 degrees Celsius and relative humidities of 50-70 percent. At more thermally stressful conditions, e.g., higher ambient temperature and the same or higher relative humidity, the experimental results show that lower SAR's cause a similar biological effect. For example, Rugh et al. (1974) found that the lethal dose of 2450-MHz radiation for mice was inversely related to a temperature-humidity index. Gage (1979b) showed that a 2450-MHz exposure at 22 degrees Celsius resulted in a reduced behavioral response rate in rats at 3 W/kg, but that similar exposures at 28 degrees Celsius caused reduced response rates at 1, 2, and 3 W/ kg.

(f) No consistent biological effect has yet been found with molecular and subcellular systems exposed in vitro to RF radiation other than effects occurring at SAR's that cause general temperature increases. Conclusions regarding effects of in vitro exposure of higher-order biological systems, such as single cells and brain tissue, are given below.

(g) The electrophysiological properties of single cells, especially the firing rates of neurons in isolated preparations, may be affected by RF radiation at SAR's as low as 1 W/kg in a manner different

from generalized heating.

(h) In general, no changes in chromosomes, DNA, or reproductive potential of RF-exposed animals have been reported and corroborated in the absence of significant rises of temperature. Similarly, RF radiation does not appear to cause mutations or genetic changes in bacterial test systems unless temperatures well above the normal physiological range are produced.

(i) Effects on the hematologic and immunologic systems have been reported at SAR's equal to and greater than 0.5 W/kg; however, there is a lack of convincing evidence for RF radiation effects on these systems without some form of thermal involvement. Some of the reported effects of RF radiation on the hematologic and immune systems are similar to those resulting from a stress response involving the hypothalamic-hypophyseal-adrenal axis or following administration of glucocorticoids. In those few cases where the reversibility of RF radiation

effects on the hematologic and immunologic systems has been examined, the effects have proved to be transient.

(j) RF radiation is teratogenic at high SAR's (greater than 15 W/kg) that approach lethal levels for the pregnant animal. High maternal body temperatures are known to be associated with birth defects. There appears to be a threshold for the induction of experimental birth defects when a maternal rectal temperature of 41–42 degrees Celsius is reached. Any agent capable of producing elevated internal temperatures in this range, including RF radiation, is a potential teratogen. [Additional information on teratology is given further in this Section.]

(k) Reduced fetal mass (low birth weight) seems to occur consistently in rodents exposed during gestation to teratogenic levels of RF radiation, or at SAR's somewhat less than those which cause death or malformation.

(l) There is evidence that exposure of rodents during gestation to RF radiation may cause functional changes later in life. For example, Johnson et al. (1978) observed lower body weight at weaning and in young adult rats exposed at 2.5 W/kg for 20 h/day during 19 days of gestation, and Chernovetz et al. (1975) found increased postnatal survival of mice exposed at 38 W/kg for 10 minutes during gestation. These studies illustrate the different effects that have been observed for chronic low-level versus acute high-level exposures. Also, Rugh (1976a) has shown that RF irradiation on select days in vitro can alter later (sometimes much later) effects of reirradiation with microwaves.

(m) Permanent changes in reproductive efficiency have been directly associated with RF radiation exposures that caused temperatures in animal testes greater than 45 degrees Celsius. At temperatures of 37–42 degrees Celsius, mature sperm may be killed with a temporary loss of spermatogenic epithelium. Irradiation of rats at an SAR of 5.6 W/kg, which produced a core temperature of 41 degrees Celsius, resulted in temporary infertility.

(n) Neurons in the central nervous system (CNS) of experimental animals have been reported to be altered by acute high-level and by chronic low-level exposures (equal to or greater than 2 W/kg). Pulsed RF radiation may have a potentiating effect on drugs that affect nervous system function. Some of the early reports of RF radiation effects on the blood-brain barrier (BBB) at SAR's equal to or less than 2 W/kg have not

been substantiated by later investigations.

(o) An increased mobilization of calcium ions occurs in brain tissue exposed in vitro to RF radiation, amplitude modulated at frequencies recorded in the electroencephalogram (EEG) of awake animals. The response appears to be based on the intensity of the electric field within the tissue, which can be related to SAR; the lowest effective SAR in in vitro samples is estimated to be 0.0013 W/kg. Calciumion efflux is a nonlinear effect in terms of both AM frequency and field intensity; that is, the response occurs at specific frequencies and electric field strengths. The physiological significance of this effect has not been established.

(p) Some types of animal behavior are disrupted at SAR's that are approximately 25–50 percent of the resting metabolic rates of many species. For example, changes in locomotor behavior in rats occur at an SAR of 1.2 W/kg, and alterations in thermoregulatory behavior in squirrel monkeys occur at an SAR of 1 W/kg. Decreases in other operant or learned behavioral responses during exposure have been found at an SAR of 2.5 W/kg in the rat and at 5.0 W/kg in the rhesus monkey. The reported behavioral alterations appear to be reversible with time.

(q) Changes reported in endocrine gland function and blood chemistry are similar to those observed during increased thermoregulatory activity and heat stress, and are generally associated with SAR's greater than 1 W/kg. Exposures of sufficient intensity to produce whole-body heating produce an increase in heart rate similar to that caused by heating from other sources. Changes in whole-body metabolism have been reported following exposures at thermal levels (approximately 10 W/ kg), and brain energy metabolism is altered at levels as low as 0.1 W/kg following irradiation of the exposed surface of the brain of anesthetized animals.

(r) Pulsed RF radiation in the range 216–6500 MHz can be heard by some human beings. The sound associated with the "RF hearing" varies with pulse width and pulse-repetition rate and is described as a click, buzz, or chirp. The threshold for human perception of this effect is approximately 40 microjoules per square centimeter (incident energy density per pulse), or 40 microwatt-seconds per square centimeter per pulse. The most generally accepted mechanism for the RF-auditory sensation is that the incident pulse induces a minuscule but rapid thermoelastic expansion within

the skull, which results in a pressure wave that is conducted by the bone to the cochlear region of the ear.

(s) For the broad range of frequencies between 0.5 MHz and 100 GHz, cutaneous perception of heat and thermal pain may be an unreliable sensory mechanism for protection against potentially harmful RF radiation exposure levels. Many frequencies deposit most of their energy at depths below the cutaneous thermal receptors.

(t) There is no convincing evidence that exposure to RF radiation shortens the life span of human beings or experimental animals or that RF radiation is a primary carcinogen (cancer inducer); however, (1) few studies have used longevity or cancer incidence as end points, and (2) human studies have lacked statistical power to exclude life shortening or cancer. There is evidence from one group of investigators that chronic exposure to RF radiation (SAR=2 to 3 W/kg) resulted in cancer promotion or cocarcinogenesis in three different types of tumors in mice; the incidence of cancer was comparable to that observed in mice exposed to chronic stress.

(u) Human data are currently limited and incomplete but do not indicate any obvious relationship between prolonged low-level RF radiation exposure and increased mortality or morbidity.

including cancer incidence.

(v) The prospects for revision and refinement of the major conclusions and generalizations stated above are considerable because of limited knowledge of (1) effects of most frequencies in the range 0.5 MHz to 100 GHz; (2) effects of chronic low-level exposures on human beings and laboratory animals; (3) which segments of the population are most sensitive; (4) the influence of ambient environmental conditions and of potential synergistic interaction with other agents; (5) the implication of nonhomogeneous RFenergy deposition; (6) the existence and significance of frequency-specific effects and power-density windows; and (7) the physical mechanisms of interaction at low exposure levels, including fieldspecific phenomena.

(w) The central nervous system, the hematologic and immunologic systems. and behavior appear to be most sensitive to disturbance by RF radiation exposure. In particular, behavior is considered to be a sensitive function to evaluate adverse responses to hazardous agents since it indicates how well the whole organism, and especially the nervous system, is functioning. The ANSI, for instance, concluded both that the most sensitive measures of biological effects were based on

behavior, whole-body average SAR's between 4-8 W/kg were associated with thresholds of behavioral disruption, and reliable evidence of hazardous effects is associated with whole-body average SAR's above 4 W/kg (17). The decrease in behavioral response rates cited by ANSI were based on studies done at ambient temperatures of 20 to 25 degrees Celsius. Additional research at EPA has shown that similar changes in behavior occur at lower SAR's when exposures are conducted at higher ambient temperature; that is, at 22 degrees Celsius (25). The effective SAR was 3 W/kg, whereas at 28 degrees Celsius SAR's of 1 and 2 W/kg were

effective (25). (x) In summary, the data currently available on the relation of SAR to biological effects show evidence for biological effects at an SAR of about 1 W/kg. This value is lower by a factor of 4 than 4 W/kg, the value above which reliable evidence of hazardous effects was found by ANSI (1982) following a review of the literature in February 1979. The above conclusion is based on: (a) the findings that more thermally stressful conditions result in lower threshold SARs for behavioral changes similar to those changes determined by ANSI (1982) to be the most sensitive measures of biological effects, (b) the effects on endocrine gland function, blood chemistry, hematology, and immunology that appear to result from some form of thermal involvement due to absorbed RF energy, and (c) data from one laboratory showing that RF radiation can act as a cancer promoter or carcinogen and results from another laboratory describing changes in brain

cellularity The SAB Subcommittee on the Biological Effects of Radiofrequency Radiation reviewed the document, Biological Effects of Radiofrequency Radiation, and concluded that "... it represents an adequate statement of the current scientific literature and can serve as a scientifically defensible basis for the Agency's development of radiation protection guidance. . . . " Since then, some additional information is now available for consideration by the Agency and is discussed below

The Agency received information and comment on biological effects from the National Institute of Occupational Safety and Health (NIOSH) that included the following (38):

(a) Certain data on teratogenicity were not available for inclusion in EPA's health effects review document. Based on research at NIOSH, malformations have been seen at SAR's as low as 8-9 W/kg, and severe teratogenic effects center around SAR's

of 10 W/kg, rather than the 15 W/kg cited in the EPA report.

(b) The EPA report stated that acute whole-body exposure of laboratory animals at SAR values greater than 30 W/kg is lethal; however, the report did not specifically analyze lethal levels of exposure and lethality data. The NIOSH identified relevant reports in the scientific literature and noted that exposures can lead to death in animals at SAR's as low as 4 W/kg. NIOSH also stated it is helpful to point out that SAR's resulting in lethality are generally lower for larger animals than for smaller animals and are quite low for monkeys (and presumably man).

(c) Severe heat stress has been reported in multiple species at dose rates (SAR's from 4-8 W/kg) that are lethal if exposure is of sufficient duration. Core temperature increases resulting from such exposures generally

are 3 degrees Celsius or more.

(d) Whole-body average SAR's from 2-30 W/kg cause death, embryonic and fetal resorption, cellular necrosis, severe heat stress, excessive increases in core temperature, reduced body and organ weight, extreme agitation, suppression of behavior, fatigue, inhibition of mitosis, and other clearly adverse effects in laboratory animals.

A study at the University of Washington was recently completed and examined the long-term effects in rats exposed throughout their lifetime to pulsed microwave radiation at a maximum average SAR of 0.4 W/kg. The eighth report in a series of published reports on this study details these latest results (39). There were generally no differences between control and exposed animals except for some evidence of (1) altered immune function, (2) increased weight of adrenal glands in exposed animals, and (3) a statistically higher incidence of primary malignancies in exposed animals.

Because of the potential significance of these data for human health, EPA intends to review this study. The following issues are important to

consider:

(a) Many clinical and biological measurements were made in the University of Washington study. It is, thus, possible that some differences would be noted that are due to chance alone.

(b) The reported tumor incidence in the exposed group of animals was not significantly different than unexposed groups of the same type of animals reported in the scientific literature; that is, the cancer incidence in the study's control animals was lower than expected from historical data on the

same strain and species. The validity of comparisons to historical controls will

be considered by EPA.

(c) The tumors occurred at multiple sites and were of multiple types, leaving biological interpretation open to question. On the other hand, many of the tumors were in organs susceptible to stress or to the action of cancer promoters.

(d) The study was designed to simulate chronic exposure of man to 450-MHz radiation at an incident power density of 1 milliwatt per square centimeter with an absorbed dose rate of 0.4 W/kg and, thus, to test the safety afforded by the 1982 ANSI guideline.

Other recent studies also need to be carefully evaluated by EPA. Some of these are: (a) a study on the potential carcinogenic activity of 2.45 GHz pulsed microwave radiation with an in vitro assay (40), (b) a reported increase in cancer, especially for blood-forming organs and lymphatic tissue, in a population of career servicemen in the Polish military (41), (c) a preliminary report on altered protein patterns in cerebrospinal fluid of radar workers in Sweden (42), and (d) corneal endothelial (eye) abnormalities in primates exposed to 2.45 GHz microwaves (43).

2. Consequences of Elevated Body Temperature

Heating has been the most generally understood and accepted explanation for most RF radiation effects. It is, thus, important to examine biological effects in relation to increases in body temperature (also referred to as core or rectal temperature) whether from RF radiation exposure or other sources of heat. The following information is also drawn from Biological Effects of Radiofrequency Radiation (25).

The average core temperature is approximately 37.0 degrees Celsius (98.6 degrees Fahrenheit) for humans and ranges from 36-38 degrees Celsius for most other mammals. In general, the lethal temperature is approximately 6 degrees Celsius above the average core temperature. Prolonged elevation of core temperature at 5 degrees Celsius above normal (42 degrees Celsius or 107.6 degrees Fahrenheit) is associated with heat stroke and brain damage in people. A temperature of 41.2 degrees Celsius (106.2 degrees Fahrenheit) occurs in only 1 of 1,000 people during fever. Elevated body temperature in men is associated with reduced fertility, and high maternal body temperatures are associated with birth defects.

Since high body temperatures are related to reproductive and teratologic effects, it is important to consider these effects in relation to RF radiation-

induced temperature increases. It is known that when mammalian testes. which have a normal temperature of 33-35 degrees Celsius, are heated to temperatures approaching abdominal temperatures (37-38 degrees Celsius), sterility can occur. At temperatures of 37-42 degrees Celsius, mature sperm may be killed with a temporary loss of spermatogenic tissue. Permanent changes in reproductive efficiency have been directly associated with RF radiation exposures that caused temperatures in animal testes greater than 45 degrees Celsius. In studies of healthy young men whose average body temperature was increased to 41 degrees Celsius by RF radiation exposure up to three hours, sperm numbers decreased by 60 percent at 40 to 60 days after the exposure. Also at this core temperature (41 degrees Celsius), temporary infertility in male rats exposed to RF radiation has also been reported; the whole-body average SAR was 5.6 W/kg. It can, thus, be concluded that adverse effects, albeit possibly reversible, on male fertility may occur if RF radiation exposure raises body temperature to 41 degrees Celsius. The whole-body average SAR in humans associated with this temperature is not known, but, based on mathematical models, it is expected to be greater than 4 W/kg under average environmental conditions.

RF radiation is teratogenic at wholebody average SAR's of approximately 10 W/kg or greater, and there appears to be a threshold for the induction of experimental birth defects when a maternal rectal temperature of 41-42 degrees Celsius is reached. Any agent capable of producing elevated internal temperatures in this range, including RF radiation, is a potential teratogen. Reduced fetal mass (stunting or low birth weight) also seems to occur consistently in rodents exposed during gestation to SAR's at 6 W/kg or greater for short-term exposures and at 4.8 W/ kg for longer term exposures.

Other kinds of effects have also been reported in various, animal species when exposure to RF radiation resulted in lower core temperature increases in the range of 1-3 degrees Celsius. These effects include, for example, hormonal and immunologic effects, changes in blood chemistry, and changes in behavior. But, as a general rule, exposures that produce an increase in core temperature less than 0.5 degrees Celsius have not been found to cause

detectable effects.

In most of the animal studies that report a biological effect of RF radiation, the exposures occurred at ambient temperatures of 20-25 degrees Celsius

and relative humidities of 50-70 percent. Experimental results show that lower SAR's will cause similar biological effects under more thermally stressful conditions, e.g., higher ambient temperature and the same or higher relative humidity. In other words, it is reasonable to expect that the above described biological effects associated with core temperature increases greater than 0.5 degrees Celsius, will also occur at lower SAR's if the combination of RF radiation exposure and ambient conditions is such that a similar core temperature increase results.

The results just discussed indicate that core temperature increases of 1 degree Celsius or more are associated with various health effects, and exposure to RF radiation is a source of heat which can increase core temperature. As a comparison, the Threshold Limit Value (TLV) for heat stress in the work environment established by the American Conference of Governmental Industrial Hygienists states that workers should not be permitted to continue their work when their core temperature exceeds 38 degrees Celsius, that is, 1 degree Celsius above the average normal temperature for adult human beings (44). One may conclude, therefore, that exposure to an environmental agent such as RF radiation that may cause a 1 degree Celsius rise in core temperature should be considered hazardous to relatively healthy individuals (25). It is important, then, to consider the SAR's that may be required to produce a 1 degree Celsius rise in the core temperature of human beings exposed to RF radiation.

There are few data that exist on the RF radiation exposure conditions that cause core temperature changes of up to 1 degree Celsius in human beings. Estimates, however, have been obtained from mathematical modeling (24). The results of these modeling analyses indicate that whole-body average SAR's of 1-4 W/kg for relatively short durations (1 hour) produce significant increases of about 1.0 degree Celsius in human body temperature at ambient temperatures of 25-30 degrees Celsius (77-86 degrees Fahrenheit). It is also reasonable to conclude that increases in body temperature are likely to occur at lower SAR's if exposure occurs under more thermally stressful conditions, e.g., higher ambient temperature and/or higher relative humidity. Data from experimental studies with primates are in close agreement with the results of the modeling experiments.

The evidence indicates that exposure of human beings at frequencies in the resonant region at an SAR of

approximately 1 W/kg produces significant changes in body temperature under some environmental conditions. Three additional factors should also be considered. First, a measurable increase in body temperature can be interpreted as an indication that the body is under stress. Exposure to RF radiation at SAR's below those that cause an increase in core temperature may be activating the heat-dissipating thermoregulatory mechanisms of the body to try to maintain core temperature within the normal range. Second, under many conditions of RF exposure, it is probable that some regions of the body will experience an increase in temperature due to localized RF energy absorption while the core temperature remains near normal. For example, an EPA mathematical model has shown that a whole-body average SAR of 1.4 W/kg produced a 3.6 degrees Celsius rise in temperature of the thigh although the core temperature rose only 0.5 degrees Celsius (25). Localized energy absorption is, however, not yet well characterized. Third, the general population has groups of individuals particularly susceptible to heat. [See Section 4 below.]

In summary, based chiefly on experiments with animals, RF radiation exposures which elevate core temperature by 1 degree Celsius can produce adverse effects. Results from animal experiments, especially with primates, and from thermal models of humans, indicate the SAR's associated with such core temperature increases may vary from 1 to 4 W/kg, depending on species differences and environmental variables.

3. Low-Level and Nonthermal Effects

The public health significance of biological effects at whole-body average SAR's lower than 1 W/kg is, at present, not well understood partly because the underlying mechanism(s) responsible for these low-level effects is not known. In some cases, results are from single studies and, thus, are not yet confirmed by replication. Most notable are neurological effects and effects from exposure to modulated fields, e.g., metabolic and histologic changes in the brain tissues of animals and of cells in vitro. Some of these effects are discussed below.

Many reports of effects of RF fields that are amplitude modulated at very low frequencies have not been independently corroborated (25). The major exception is calcium-ion efflux from chick brain tissue *in vitro* at intensity levels far below those that cause heating. This, combined with the results of studies of brain biochemistry

and electroencephalograms (EEGs) in animals and with synaptosomes and human neuroblastoma cells in culture. provides evidence that central nervous system (CNS) tissue from several species, including human beings, is affected by low-intensity RF fields sinusoidally amplitude modulated at specific low frequencies or by those low frequencies directly. The physiological significance of these field-induced effects is not established. In addition to the CNS-related changes, amplitudemodulated RF fields have been reported to alter an immune response and a pancreatic tissue function.

These reports with diverse biological systems are without apparent connection to each other except for the physical agent causing the change. The critical parameter common to all these experiments is the specificity of the low frequency electromagnetic signal. However, in most cases, dose response curves, namely, magnitude of the response as a function of frequency, have not been obtained.

No report has yet described a mechanism of action in sufficient detail to identify the conditions necessary and sufficient to explain unequivocally calcium ion efflux in the brain or the other biological changes caused by low frequency signals or by modulated RF fields. The response to specific frequencies and intensities is unusual and at present unexplained. This response to amplitude modulated RF radiation may be a true field effect at a very low SAR and at biologically relevant frequencies, i.e., in the range of frequencies normally present in the EEG. The evidence is against heat as the underlying cause. These unusual, multiple-intensity-range responses challenge standard dose-response analyses and, by their very nature, may prohibit the invocation of threshold levels.

Pulsed RF radiation can be perceived ("heard") by some people. The perception of sound associated with "RF hearing" varies with pulse width and pulse-repetition rate and is described as a click, buzz, or chirp. Because this effect is a function of instantaneous peak energy deposition and pulse width, average whole-body SAR's are not useful exposure parameters. Although the effects of RF hearing on health are not now known, the experience may be annoying and stressful.

4. Potential Human Health Effects

a. Introduction. Exposure to RF radiation produces various biological effects. Most studies use experimental animals exposed for relatively short periods of time, rather than long-term

continuous exposures, and few health studies of people have been done. At relatively high rates of energy absorption, health effects are due to heating of cells and tissues and increases in temperature depend on duration of exposure. Absorption of sufficient RF radiation energy, as with other sources of external heat such as sunlight, can be harmful.

Effects have also been found in experimental animals at levels that do not produce detectable temperature increases in tissue. It is not known whether these effects occur in humans or if they are harmful. Most people are exposed to even lower levels that have not been shown to result in adverse effects in experiments with animals. Despite various uncertainties in the understanding of how RF radiation exposure affects human health, it is still possible to evaluate the potential for adverse health effects in exposed people and to identify groups in the population who may be particularly sensitive to RF radiation. The potential health effects of RF radiation can best be discussed from two perspectives: thermal effects and potential nonthermal effects.

b. Thermal Effects. Humans have a "thermostat" that maintains the body's temperature at 37 degrees Celsius. The ability of the body to reach and maintain a characteristic temperature is called thermoregulation. There are a variety of thermoregulatory processes by which body temperature is maintained despite widely varying environmental temperatures. Two major ways of dissipating excess heat from the body are: (1) The diversion of blood circulation to the surface of the body to radiate body heat and (2) sweating and other fluid-dependent processes. These are involuntary physiological processes, but people also react to the perception of heat or cold with a variety of voluntary actions including changing location, altering temperature settings in contained spaces, and changing clothing. We also respond to the thirst caused by sweating. An understanding of thermoregulatory processes helps to interpret the levels of RF radiation that are likely to produce adverse effects and to estimate what types of people would be particularly susceptible to such effects. Two levels of RF radiation are important to consider: (1) The level that significantly raises deep body temperature, called the core temperature, and (2) the level that is of sufficient intensity to produce a detectable change in involuntary human thermoregulatory responses.

For the first level of concern, increases in body core temperature of roughly 1 degree Celsius appear to occur at SAR's of 1-4 W/kg. The actual increase in temperature is strongly dependent on exposure duration and ambient conditions. Raising the body core temperature could be adverse for a healthy individual. At the least, such an effect can be considered an abnormal stress on bodily processes that would be particularly serious to those individuals with preexisting significant acute or chronic disease. The health consequences would obviously be more severe at higher levels of RF energy absorption. But RF radiation levels that only begin to increase body temperature on an acute basis should not be automatically considered to pose an acute health threat because there is a normal daily variation in body temperature as well as changes in body temperature due to hormonal rhythms. Furthermore, people are subject to increased body temperature as a result of illness-fever. The onset of increased body temperature should be considered to be a potential adverse health effect to be avoided, but, at its lowest levels, the effect will rarely be adverse.

The second RF radiation level of concern is the lower level of exposure that activates the body's thermoregulatory responses. The onset of this effect appears to occur roughly at or above 0.4 W/kg. Merely turning on or off usual thermoregulatory mechanisms should not in itself adversely affect health, but it is most certainly a measureable physiological change, and certain people might be more susceptible to such changes. Also, of obvious concern would be individuals who have lost one or more of the thermoregulatory responses that normally help dissipate heat. Such people would be anticipated to have an increase in body core temperature at a level of RF radiation exposure lower than the level required to increase body core temperature in individuals with uncompromised thermoregulatory mechanisms. The people most at risk would be those who are unable to move voluntarily; that is, lack of voluntary motion would preclude obtaining liquids in response to sweat-induced loss of fluid, changing locations, changing clothing, altering indoor temperature settings, or moving about to dissipate body heat. Infants would have to cry and would depend on an adult to provide relief. Presumably, people with vascular disease would be particularly affected because their circulatory problems could affect their thermoregulation. One could also speculate that an individual who was already thermally stressed, for example,

with a fever, also may be at risk. Furthermore, it is also possible that pregnant women may be more susceptible to heat stress. The people most likely to be most severely affected by RF radiation below the SAR's of 1-4 W/kg that raise body temperature would be elderly infirm individuals who are also immobile. Also, dehydration is a factor that can aggravate a number of adverse conditions in such individuals.

Groups of individuals particularly susceptible to heat stress were identified by Ellis (45) who examined the Vital Statistics Reports of the U.S. Public Health Service for the years 1952-67. Heat waves had occurred in five different years during that period. Excess deaths, especially for various forms of heart and circulatory disease, were found to be associated with the heat-wave periods. It was also concluded that infants less than one year of age are the most heatsusceptible group below age 50 and adults over 50 years of age are more heat-susceptible than infants and become progressively more susceptible with advancing age. Consideration should perhaps be given to the health impact of the thermal extremes that can exist in the U.S. during summer months.

c. Nonthermal Effects. There are a number of effects described in the scientific literature that occur at levels equal to or less than 0.4 W/kg, and these are generally not associated with increases in temperature. For example, it has been experimentally observed that the efflux of calcium ions from animal brain tissue is enhanced after exposure to low intensity RF energy under certain discrete conditions. Calcium ions are important to several physiological functions, particularly in the nervous system. There are many reasons why there could be changes in ion movement, and the extent to which this effect might indicate a hazard to humans is not presently known. Further research is needed to determine the relevance, if any, of this phenomenon to human health.

Other studies have endpoints that may be of more concern. One example is the recently reported study involving long-term exposure at 0.4 W/kg in which rats were found to have enlarged adrenal glands and an increase in overall tumor incidence, although there was no statistical increase in any particular type of tumor.

The overall implications for human health of low-level nonthermal effects is not clear, and in some cases there are conflicting data on whether a given effect occurs. Further research is required to determine the generality of these low-level effects and whether they constitute a hazard to human health.

d. Summary. One mechanism by which RF radiation produces effects is by heating the human body. The increase in body core temperatures due to RF radiation is reported to occur at SAR's of 1-4 W/kg. This should be considered an adverse health effect. But short-term small increases in body temperature should be of relatively minimal health concern. It is possible that lower SAR's could also increase core body temperature in hot and humid environments, especially in those people with impaired thermoregulatory processes and particularly in individuals who are immobile; the threshold would be expected to be that RF radiation level that causes the onset of thermoregulatory processes and apparently could occur at about 0.4 W/ kg or above.

The scientific literature also contains evidence intimating nonthermal effects from RF radiation, but whether such effects would affect the health of people is not yet clear. Several recent studies, including one said to show a nonspecific increase in tumors in laboratory animals chronically exposed at 0.4 W/kg, need to be analyzed.

5. Conclusion

Based on the currently available biological effects data, EPA has concluded that adverse human health effects are associated with whole-body average SAR's of 1 to 4 W/kg or greater. However, data are insufficient to assess the adversity and human health implications of effects that occur below this level, and this leaves potentially significant issues unresolved. Effects in question include, among others, those associated with low-frequency modulated RF fields, the potential for cancer promotion, and frequency specific effects such as changes in brain energy metabolism.

D. Approach to the Derivation of Exposure Limits

Because they are believed to have mechanisms of action that exhibit thresholds, agents producing noncarcinogenic health effects are generally evaluated differently than carcinogens. For noncarcinogens, public health regulatory agencies, including EPA, typically have applied preselected safety factors to no-observed-effect-levels (NOELs) or other parameters to determine the level below which human exposure should fall (46–50). A safety factor in health protection standards does not guarantee safety; it represents, instead, an attempt to compensate for

unknowns and uncertainties. Safety factors or, more appropriately, uncertainty factors typically range from 10 to 1000, depending on the type of available data, e.g., human versus animal, acute versus chronic, and so forth. Although selection of the actual level of a factor is largely judgmental, uncertainty factors are used to account for several areas of uncertainty such as intra- and inter-species variations in response to an agent; sensitive human sub-populations, e.g., the ill; possible synergistic interactions; the greater probability of risk in the human population that is larger than the number of animals that can be tested; and other considerations. Uncertainty factors of 100 have most traditionally been used and essentially contain a 10fold factor to account for interspecies differences and a 10-fold factor to account for uncertainties when extrapolating from high to low doses. Also, in establishing standards for many agents, a common practice has been to assign a 10-fold factor to occupational exposures and an additional 10-fold factor to exposures in the general population. The difference is related primarily to the lack of consent to and knowledge of the exposures and the greater diversity in the general population which contains a wider range of ages and more susceptible subgroups than does a presumably more healthy working population.

Developed from reviews of basically the same information, the various existing criteria or recommendations for RF radiation exposure essentially differ only in terms of the applied margin of safety. Using a starting point of an SAR of 4 W/kg, the ANSI applied an uncertainty factor of 10 to develop its recommendation of 0.4 W/kg for workers and the general population but stated that this level should be viewed as an upper limit of exposure especially for the general population (17). The Massachusetts standard, the IRPA interim guideline, and the NCRP recommendation each used an uncertainty factor of 50 to derive an exposure limit of 0.08 W/kg, a level five times more stringent than ANSI to afford greater protection for the general population. Portland, Oregon has used zoning guidance of 0.04 W/kg; this is 10 times more stringent than the ANSI voluntary standard and is equivalent to applying an uncertainty factor of 100 to a SAR level of 4 W/kg.

On the basis of the available data, the Agency believes RF radiation should, for now, be treated as a noncarcinogen, and an uncertainty factor should be used in deriving exposure limits, especially in view of the remaining uncertainties in our knowledge of the health effects of RF radiation exposure. But, because of the degree of judgment involved in selecting any uncertainty factor, comments are solicited on this matter and specifically on the following issues that relate to the magnitude of an uncertainty factor:

(1) Reasonably precise and reproducible information is typically obtained from experimental animals. Nevertheless, there are still likely to be sensitivities that may go undetected and results can vary even under the best of conditions (46). Any series of experiments can yield false-positive and false-negative results (47). Use of a safety factor helps compensate for experimental and statistical uncertainties.

(2) The extent and validity of animal data is an important consideration in determining an appropriate margin of safety. For RF radiation, there are multiple studies in different animal species. This body of data has led to some degree of consensus within the scientific community on what constitutes adverse effects levels, and this would tend to lessen the need for a large margin of safety.

(3) Much of the biological effects data from animal experiments is, however, based on relatively short exposures. There are uncertainties associated with extrapolating data from short duration exposure to long-term exposure both in animals and people. Lack of data on long-term exposures could be highly significant since environmental exposure of the public generally occurs continuously over a long period of time.

(4) There are also uncertainties associated with extrapolating data from test animals to human beings. Because of interspecies differences, human responses may not correspond to animal responses to comparable exposures.

(5) Unlike experimental animals, humans are genetically very diverse, exhibit varying susceptibilities, and live in a heterogeneous environment. Use of a safety factor is indicated since it is not possible to estimate effects of all the genetic and environmental variation in the general population (46). Subpopulations at potentially greater risk from exposure to RF radiation have not yet been well characterized, although it is known that the body's ability to handle high temperatures and humidity depends on age and health condition.

(6) In experimental animals, the whole-body average SAR required to produce a given effect depends on the environmental conditions accompanying

the RF radiation exposure. The SAR level at which adverse effects occur in humans might also be expected to depend on environmental conditions, but actual data are not presently available. A safety factor might, then, be needed to account for the predictable influence of adverse environmental conditions on both healthy and susceptible populations exposed to RF radiation.

(7) Certain biological effects that do not seem to be due to heating occur below the l to 4 W/kg range, but there is no evidence to indicate whether and under what conditions these effects are adverse or persistent. Prudence would seem to dictate use of a safety factor because of the possibility that the effects observed below l W/kg may prove to be biologically significant.

(8) In setting health protection standards, there has been a tradition of differential margins of safety between occupational and general population standards on the basis that different levels of knowledge, consent, and health, as well as exposure time, exist in the affected groups. As mentioned in the discussion of existing standards, the ANSI selected a safety factor of 10 to derive its recommended exposure limit. Both the IRPA and NCRP concluded that a larger margin of safety should be applied to aderive exposure limits for the public, and we seek comment on this

(9) At some frequencies, RF radiation energy is generally deposited deep in the body below cutaneous thermal receptors; therefore, cutaneous perception of heat and thermal pain may be an unreliable sensory mechanism for protection against potentially harmful RF radiation exposure levels. This means the body may not "recognize" or react to RF radiation energy as quickly or in the same way as it does to other sources of thermal loading or heating. This bypass or delay in response of the body's adaptive protective mechanism would argue for a larger margin of safety

(10) On the other hand, the human thermoregulatory system is more adaptive than most fur-bearing animals, primarily because of the ability to secrete sweat on the skin. Extrapolating thermoregulatory data from animals to humans is, therefore, difficult and a one-to-one relationship may be overly conservative. This would tend to argue for a smaller margin of safety.

(11) The biological effects data indicate that the larger the animal, the lower the effective SAR required to produce many types of effects. This might indicate that any uncertainty

factor should account for the greater mass of humans compared to experimental animals. But, for thermoregulatory responses, this is a much debated issue, related to the concerns noted in #10 above.

(12) The whole-body average SAR is an estimate of absorbed energy averaged over the whole-body mass. It is currently the parameter most used to describe energy absorption in biological systems. Because of limits associated with measurement of the SAR in individuals, the whole-body SAR must be computed on a theoretical basis, and it does not directly address the existence of localized areas in the body of increased energy deposition ("hot spots"). For example, the SAR within a specific body tissue can exceed the whole-body average SAR by a factor of 100 or more, depending on frequency and orientation of the body (51). The uncertainties associated with localized versus whole-body energy absorption would tend to argue for a larger margin of safety.

(13) Analytical and experimental studies have shown that SAR is dependent on whether an individual is electrically grounded or ungrounded. For grounded conditions, SAR may be as much as twice the ungrounded value at identical exposure conditions, and the maximum value typically occurs at a new lower resonant frequency. Virtually all of the SAR's derived from animal experiments described in the literature where direct assessment of SAR was not reported are based on the assumption of ungrounded conditions. Since people are generally grounded, consideration of the SAR's for grounded conditions could be made in deriving permissible RF radiation exposure field strengths.

(14) The severity and health consequence of any given effect is an important consideration, e.g., cancer has more severe consequences for the individual than does transient respiratory illness. But one of the major problems in attempting to assess the health risks from RF radiation exposure is that the observed biological effects are diverse and have not yet been linked, through research, to a given disease, condition, or set of distinct symptoms in people. (The scientific literature from the Soviet Union and Eastern Europe has, however, discussed the occurrence of "microwave sickness" or a "neurasthenic syndrome.") In fact, there is accumulating evidence that RF radiation acts as a generalized environmental stressor, via the mechanism of heating, and, as such, could precipitate or exacerbate a host of physiological conditions and clinical states with varying degrees of severity. This makes the choice of an appropriate margin of safety very difficult.

(15) Human exposure to low levels of RF radiation has occurred without obvious untoward effects, and this should also be considered in establishing a margin of safety. On the other hand, very few carefully controlled analytical epidemiological or clinical studies have been done. It is difficult in epidemiological studies to detect low probability risks in general and if RF radiation can produce varied effects as a generalized stressor (see #14 above), it would be difficult to identify and detect subtle or diverse changes even in a well-designed study with a large sample size.

(16) Nonreversible effects may require a larger margin of safety than do reversible effects. When evaluated, many of the biological effects from RF radiation exposure are reversible after exposure stops. Low birth weight may, however, persist for a significant period of time in young animals after exposure ceases (52). Reversibility would argue for a smaller margin of safety. The ANSI, however, took the position that, for behavioral effects, "reversible disruption during an acute exposure is tantamount to irreversible injury during chronic exposure." (17) [See also #3 abovel

(17) Integral to any uncertainty factor analysis is determination of the pertinent threshold to be used as a starting point, be it a no-observedadverse-effect-level (NOAEL) or a noobserved-effect-level (NOEL). For thermal effects, RF radiation would appear to be a threshold pollutant. But much of the research to date has not fully defined dose-response relationships because exposure levels (and resultant SAR's) have often been selected arbitrarily rather than selected to define thresholds. The biological effects data may, then, be more in line with the concept of lowest-observedadverse-effect-levels (LOAEL). A variable uncertainty factor between 1 and 10 is often applied to bring a LOAEL into the range of a NOAEL, depending on the severity of the effect (48).

(18) A smaller margin of safety may be required if the mechanism of action for an agent is well understood (48). This is the case for the thermal effects of RF radiation exposure but the mechanism of action has not been established for the presumed nonthermal effects. Because the mechanisms of action and human health implications of the low-level or nonthermal effects are not known, EPA proposes to restrict the use

of these results to margin of safety considerations.

(19) The EPA has considered biological effects in toto to determine where an overall cut off point or threshold for adverse effects appears to lie. This approach was also used by ANSI, IRPA, and NCRP. For chemical toxicants, it is more usual to select one health effect in the most sensitive species. The Agency is, therefore, interested in comments on which approach is more suitable when evaluating the effects of RF radiation exposure.

V. Additional Consideration for Frequencies Below 3 MHz

Exposure to RF radiation below 3 MHz, and particularly below 200 kHz, requires special consideration and treatment. Practical experience has shown that prevention of electrical shock can be a significant safety consideration (53). The principal area of concern for public exposure arises from the induction of RF currents in conductive objects. These induced currents may flow through the body of an individual who contacts them. The amount of current that will flow through the body of a person depends upon how well the individual is electrically grounded and the impedance between the current source and the individual. Low-frequency fields can cause potentially hazardous electric currents to flow in capacitive objects such as vehicles, fencing, metal roofing, and other ungrounded conducting objects, including the human body, when these objects become adequately grounded. EPA advises that, as a minimum, lowfrequency fields should be limited to intensities that prevent accident-causing startle reactions in ungrounded individuals who may momentarily contact grounded objects while exposed to high intensity RF fields, but is soliciting comments on this issue. This subject is discussed in greater detail in the following section.

VI. Discussion of Proposals

A. Approaches To Control Exposure to Radiofrequency Radiation

The increase in the number and type of RF radiation sources has created a RF radiation environment to which the population is continuously exposed to varying degrees, and the number of RF radiation sources is expected to continue to increase in the future. People live, work, or pass through areas near RF radiation emitting sources that can produce levels of exposure that are now known to be associated with various

effects in laboratory animals. Although EPA cannot yet fully enumerate or characterize the populations exposed to differing levels of RF radiation, measurement and modeling analyses by the Agency have provided information on the number and characteristics of sources likely to produce high exposures. For example, it is predicted that over 1,100 existing broadcast sites exceed the current ANSI guideline.

EPA's overall objective is to prevent adverse health effects that may be associated with exposure to RF radiation in the environment. By this Notice, EPA solicits comment on four options, three regulatory and one nonregulatory, that it has developed as alternative approaches to control exposure to RF radiation. Depending on how they are implemented, all options should achieve the Agency's objective of reducing or preventing adverse health effects, although with varying degrees of confidence. It is assumed that a margin of safety is needed given current uncertainties in translating from experimental animal data to human exposures and effects and in predicting sensitive populations and effects under conditions of environmental extremes. It is also assumed that the greater the margin of safety, the greater the likelihood that adverse health effects can be reduced or prevented.

The proposed options encompass the range of limits recommended or adopted by various advisory groups such as the International Radiation Protection Association (IRPA), the National Council on Radiation Protection and Measurements (NCRP), and the American National Standards Institute

(ANSI), and include:

(1) Controlling public exposure by limiting whole-body average specific absorption rates (SAR) to 0.04 watts per kilogram (W/kg) for frequencies above 3 megahertz (MHz) and by limiting electric field intensity to 87 volts per meter (V/m) and magnetic field intensity to 0.23 amperes per meter (A/m) at frequencies below 3 MHz.

(2) Controlling public exposure by limiting whole-body average SAR's to 0.08 W/kg for frequencies above 3 MHz and by limiting electric field intensity to 275 V/m and magnetic field intensity to 0.73 A/m for frequencies below 3 MHz.

(3) Controlling public exposure by limiting whole-body average SAR's to 0.4 W/kg for frequencies above 3 MHz and by limiting electric field intensity to 614 V/m and magnetic field intensity to 1.63 A/m for frequencies below 3 MHz.

(4) In lieu of adopting Federal Guidance for RF radiation, establishing public awareness programs to distribute information on health effects and environmental measurements as well as provide technical assistance to States

and Federal agencies.

The nonregulatory option, Option 4, would not establish Federal Guidance but would provide and continue to develop technical information that others could use to establish controls. Option 3 would protect healthy people in normal environments against the adverse thermal effects of RF radiation exposure. Options 1 and 2 incorporate respectively larger safety factors and, thus, offer increasing degrees of assurance that adverse health effects would be prevented and the potential for other effects would also be reduced.

Because of the substantial uncertainties in the available health effects information and the complex character of RF radiation exposures, the Administrator wishes to solicit the fullest possible participation and comment by the public before deciding which Guidance levels, if any, should be recommended to the President. The EPA seeks comments on its overall objective, on the adequacy of each of the proposed approaches for protecting public health, and on the following specific issues and questions:

1. Each of the alternative approaches has advantages or disadvantages, discussed below, that will be considered

by the Administrator:

(a) Option 1—Guidance Based on an SAR of 0.04 W/kg. This option represents a "no effects" level by protecting against thermally-related health effects in humans, including most sensitive subgroups of the population. No measurable changes in core temperature would occur at this level nor would any thermoregulatory responses be initiated. This level is consistent with the usual practice of providing substantially more protective standards (here, by a factor of 10, when compared to, for example, the 1982 ANSI voluntary standard of 0.4 W/kg) for the public than those recommended for occupational exposures. This level might be viewed as unnecessarily stringent in that the health protection provided may not be commensurate with its cost, particularly in view of the present uncertainties surrounding lowlevel and nonthermal effects.

(b) Option 2—Guidance Based on an SAR of 0.08 W/kg. This option also effectively represents a "no effects" level by protecting against thermally related health effects in humans, including most sensitive subgroups of the population. No changes in core temperature should occur at this level nor should any thermoregulatory responses be initiated. Also consistent with the usual practice of generally

providing more protective standards for the public than those recommended for occupational exposures, this level differs from Option 1 in that it is lower than, for example, the 1982 ANSI guide by a factor of 5 rather than a factor of 10, as given in Option 1. This option is similar to the Massachusetts standard, to the IRPA guideline in the resonant frequency range, and to the exposure limits recently recommended by the NCRP. The Agency is particularly interested in comment on this option, because 42 U.S.C. 2021(h) states that the Administrator shall consult with the NCRP, among others, on radiation matters.

(c) Option 3-Guidance Based on an SAR of 0.4 W/kg. This option should protect against thermal effects except in possibly more susceptible or sensitive people or possibly at high ambient temperatures and humidities. This level corresponds to the lower end of the range postulated to be associated with the onset of thermoregulatory responses in humans. Effects that occur below this level do not, for the most part, seem to be caused by generalized heating. The 1982 ANSI standard, set at this level, does not differentiate between occupational and public exposure but noted, ". . . these guides are offered as upper limits of exposure, particularly for the population at large." (17) Various groups in the broadcasting industry have indicated to EPA their willingness to comply with a guideline at this level (letters placed in the Central Docket). The Agency is particularly interested in comment on this option, because it is similar to the 1982 ANSI guide voluntarily adopted by much of the broadcast industry and is to be used by the FCC to determine the need for environmental impact analyses for new and renewal license applications.

(d) Option 4-Conduct Other Activities in Lieu of Adopting Federal Radiation Protection Guidance for RF Radiation. This is a nonregulatory option, and it would provide public health protection only as it is realized indirectly through the advice and technical assistance provided by EPA to Federal agencies, States, or industry. Taking no regulatory action at this time could permit any further regulatory action to be based on more refined biological, technical, and economic analyses. For example, allowing more time for additional research to identify and quantify adverse health effects in the population may result in more improved risk estimates. It is not clear whether this approach will meet the perceived need of Federal agencies, States, or industry that have requested

uniform Federal exposure guidelines, and EPA seeks comments on this issue.

2. An analysis of the potential economic impacts associated with each of the regulatory approaches indicates that the range of costs differs by about a factor of three. The estimated costs and number of affected sites are discussed in Part VII of this Notice. The Agency solicits comment on its analysis of the potential economic impacts of establishing Federal Guidance for radiofrequency radiation.

In addition, EPA is also interested in comments on costs relative to the degree of health protection afforded by each option. As the degree of stringency or health protection increases, the estimated costs of compliance also increase. Costs roughly double between each option while the presumed gain in health protection increases five-fold between Option 2 and 3 but only twofold between Option 1 and Option 2. Also, changes in regulations over time can impose additional costs of compliance as, for example, systems are adapted or retrofitted to comply with updated regulations, be they more restrictive or loosened. If any future research more clearly indicates adverse human health effects could result at low levels of exposure, it is least likely that any RF radiation Guidance initially set at the level of Option 1 would have to be lowered. Option 1, then, should minimize the possibility of industry incurring additional incremental costs of compliance in the future but its current projected costs are higher than the other options. Similarly, if Guidance were ever revised downward from the level proposed under Option 3, there could be some disruption to industry, involving additional incremental costs for compliance. The Agency is interested in comment on these issues as well as on the degree to which cost should be considered in establishing Guidance.

3. EPA has determined that adverse effects can begin to occur between 1-4 W/kg. The degree of severity depends on the sensitivity of the individual, the duration of exposure, environmental conditions, and the amount and persistence of a change in core temperature. Temperature changes of up to 1 degree Celsius that occur intermittently and for short durations are not likely to be hazardous for most people. But sustained temperature increases of this magnitude can be adverse, especially in more sensitive individuals. The onset of thermoregulatory responses appears to fall in the range of 0.4-1 W/kg; such changes are not likely to be adverse for most people. Effects below this level are

presumably nonthermal in origin, and their relative adversity is not established. As noted in Section IV.D, the Agency believes RF radiation should now be treated as a noncarcinogen, and safety or uncertainty factors should be applied to derive exposure limits. With this background, the uncertainty factors applied in establishing the proposed options levels, in the resonant frequency range, are:

		Uncertainty factors				
Option	SAR (W/kg)	"Adverse Effects" 1-4 W/kg	"Ob- served Effects" 0.4-1 W/kg			
Option 1:	0.04	25-100	10-25			
Option 2:	0.08	12.5-50	5-12.5			
Option 3:	0.4	2.5-10	1*-2.5			
Option 4: no exposure	Harry .					
limit		NA	NA			

1* Means no uncertainty factor applied. Because of the degree of judgement involved, the Agency seeks comments on the range of uncertainty factors above and the degree of health protection afforded, considered in the context of the issues discussed in part IV.D of this Notice.

4. There are some preliminary and unconfirmed studies on RF radiation exposure and carcinogenesis. The SAR's of interest fall in the range between 0.4–4 W/kg. The potential role of RF radiation exposure in carcinogenesis is not yet resolved and could affect EPA's assessment of adverse health effects levels and the treatment of RF radiation as a noncarcinogen. The Agency seeks comment on this issue.

5. A need for a uniform Federal guideline has been expressed to EPA, primarily by industry and other Federal agencies. EPA has no preemption authority under Federal Guidance and so uniformity cannot be enforced. It is not clear whether States, cities, or other local authorities would adopt any EPA Guidance although some jurisdictions have indirectly indicated their willingness to do so (letters placed in Central Docket). The degree of acceptance might depend on the actual level of any Guidance. To provide additional information to help resolve this question, EPA seeks specific comments on the need for a Federal guideline, its degree of acceptance at nonfederal levels of government, and whether Federal Guidance could foster uniform and consistent exposure limits nationally.

6. There are many uncertainties when assessing the health risks of RF radiation exposure. There are potential costs associated either with establishing an overly conservative limit or with establishing a too lenient guideline that must eventually be revised downward. The Agency must determine whether it is better to establish Guidance now or to delay until and if more refined scientific

information becomes available, as proposed in the fourth nonregulatory option. The Agency is interested in comment on this matter.

7. EPA is proposing that Guidance, if any, should apply to the frequency range between 10 kHz and 100 GHz and that, over this range, the average whole-body specific absorption rate (SAR) be controlled at a constant level, i.e., at 0.04, 0.08, or 0.4 W/kg depending upon the option ultimately chosen. However, it is recognized that at the lower frequencies it may also be desirable to prevent electrical shocks and RF burns which can occur because of induced currents caused by RF fields. Induced currents occur in individuals as well as in conductive structures exposed to RF fields. Both shock and RF burns can startle people, possibly leading to accidents. To help prevent shocks and burns, it is necessary to limit the electric and magnetic field strengths to levels less than might be allowed by a constant specific absorption rate. The electric field strengths proposed in Options 1, 2, and 3 are 87, 275, and 614 V/m, and the magnetic field strengths proposed are 0.23, 0.73 and 1.63 A/m, respectively. These levels approximate the different limits recommended by the International Radiation Protection Association (IRPA), the State of Massachusetts, the NCRP, and the American National Standards Institute. The IRPA applies the values 87 V/m and 0.23 A/m to frequencies below 1 MHz, and Massachusetts, NCRP, and ANSI apply their limits to frequencies below 3 MHz. Although the IRPA, Massachusetts, and NCRP general population limits are similar, the IRPA limits for low frequencies are more stringent because "exposure limits should not be so high that RF shocks could occur, since it would be totally unreasonable to require this group (the general public) to take precautions to avoid shocks." (20)

EPA is soliciting comment on the values of electric and magnetic field strength to use to prevent perception, shock, and RF burns; on the frequency where these phenomena begin to predominate, i.e., l or 3 MHz; and on the lowest and highest frequencies to which Guidance should apply. [Low frequency fields are also discussed in Section B.2 below.]

8. EPA is interested in comment on whether Guidance should apply under all environmental conditions regardless of the air temperature, humidity, air speed, and electromagnetic energy input from sources outside the proposed frequency range. The margin of safety incorporated into Options 1 and 2 may

eliminate the need to modify the Guidance for application in hot, humid environments, but this may not be so for the limits proposed in Option 3, especially for sensitive individuals.

B. Other Considerations

1. Continuous Exposure Between 3 MHz-100 GHz: The limits proposed in Options 1-3 for the 3 MHz-100 GHz frequency range would control the whole-body average SAR by incorporating the frequency dependence of energy absorption. This frequency dependence includes a consideration of exposure conditions which provide for maximum coupling with the electromagnetic field. Because RF radiation is not uniformly absorbed by the body tissues, specific tissue SAR values can exceed the whole-body average SAR. Depending upon frequency, the ratio of the maximum tissue SAR's to whole-body average SAR's may range from 3-10 for body resonant frequencies and may be larger. up to a factor 100, at nonresonant frequencies. It should be noted that although long-term local (in the body) SAR values are not explicitly stated, the recommended limits for continuous exposure under Option 1 will substantially minimize local heating effects of RF body currents by keeping the local SAR to less than 4 W/kg in anatomical areas of small cross-section. Options 2 and 3 would keep the local SAR to less than 8 and 40 W/kg. respectively. All options would permit short-term (less than six minute exposures) local SAR values greater than these values.

If EPA recommends Federal Guidance, the basic SAR limit adopted will be used to derive limits of exposure presented in units of root-mean-square (RMS) field strength, mean squared field strength, and plane-wave equivalent time-average power density to maximize convenience in implementing Guidance since commercially available instruments are typically calibrated in one of these units. The maximum continuous RMS electric and magnetic field strengths to which members of the public may be exposed for durations greater than one-tenth hour (6 minutes) in any hour will be defined and exposure limits in the corresponding units of mean squared field strengths and plane-wave equivalent time-average power densities will be given.

RF fields should be measured at least 10 centimeters (cm) away from radiating sources and from objects that act as secondary sources, in order to avoid erroneous instrument readings because of capacitive coupling to the object. For frequencies greater than 30 MHz,

determination of either electric or magnetic field strength is sufficient except for near-field and multipath interference situations in which both E and H field strengths should be measured. For frequencies equal to or less than 30 MHz, both electric and magnetic field strengths must be measured.

2. Exposures Between 10 kHz-3 MHz: Low frequency fields can charge capacitive objects such as ungrounded vehicles, fencing, metal roofing, and any other ungrounded conductive objects including the human body, and electric shocks or RF burns are possible. Because of this additional consideration, fields in the frequency range of 10 kHz-3 MHz could be limited on the basis of the magnitude of induced RF currents. There are established methods for calculating the magnitude of such induced RF currents in different objects (54-56), and published data describe the variation with frequency of RF currents associated with perception of induced currents and shock reactions in humans

Shock phenomena predominate over the frequency range from 10 kHz-200 kHz. The potential for accident-causing startle reactions can be reduced by limiting the current which would flow to ground from an ungrounded individual (immersed in a low-frequency field) who touches a grounded object. For all three regulatory options proposed, the current that flows from the individual through the grounded object would be less than the value of current perceivable by most individuals (the 0.5 percentile perception level) for frequencies from 10 kHz to 200 kHz

For frequencies above 200 kHz, current flow will be perceived through a heating reaction (RF-burn) at the point of skin contact, as opposed to shock. The NIOSH defined the induced current value of 100 mA as the RF burn threshold and assumed a skin contact area of 1 square centimeter (59). Using the techniques described in references 54–56, the RF field strengths permitted by each option proposed in this Notice would be expected to cause induced currents in a grounded individual as follows:

Option 1: 45 mA induced current at 3 MHz

Option 2: 247 mA induced current at 3 MHz

Option 3: 553 mA induced current at 3 MHz

Thus, EPA's proposed Options 2 and 3 exceed the RF-burn threshold proposed by NIOSH, but Option I does not.

Even when RF fields are substantially less than the levels prescribed in the

various options, exposures at low frequencies can cause high values of electrically induced currents to flow from large conducting objects to a grounded individual. But, because of the very wide variety of conducting objects in the environment and the diverse opportunities for humans to contact these objects, it is impractical to specify numerical electromagnetic field intensity limits that prevent all possible shock and RF burn effects. Thus, although any Guidance would specify maximum exposure field intensities, it is recommended that in those cases where such shock and RF-burn conditions may exist action be taken to prevent their occurrence. Such action could include reducing the strength of the fields. preventing access by the public to the area or object(s) of concern, or grounding of the conducting object(s).

3. Short-Term Exposures: The EPA will consider establishing short-term exposure limits substantially higher than continuous exposure limits. The rationale behind permitting higher intensity exposures of limited duration is that commonplace radiation sources can produce environmental levels above the limits specified here for continuous exposure at some locations which are accessible to the public but where there is little likelihood or reason for anyone to remain in these fields for a prolonged period of time. A short-term limit introduces an element of practicality into the Guidance by allowing transient exposure to higher levels. For frequencies less than 3 MHz, the higher exposure values are not recommended since shock phenomena are unrelated to the duration of exposure.

A six minute (0.1 hour) limit has been conventionally used in the development of short-term RF exposure criteria by ANSI regardless of frequency (17). This time interval is related to consideration of the thermal response time of the human body when subjected to shortterm RF exposures capable of raising the body temperature. For exposures less than 6 minutes (total) in any I hour, the Agency is proposing that limits be 10 times the long-term continuous exposure values permissible for all frequencies greater than 3 MHz; that is, in any hour, the amount of energy absorbed during 6 minutes will be no more than the amount absorbed in I hour at the levels

recommended for continuous exposures.

4. Pulsed Electromagnetic Fields: The health significance of exposure to pulsed electromagnetic fields is not clear. The biological effects literature does not yet provide a firm basis for limiting the instantaneous peak SAR's caused by pulsed fields. However, under Options

1-3, pulsed fields would be subject to the same limits on a time-average basis as non-pulsed fields.

EPA believes that establishment of accurately defined quantitative peak pulse field intensities is not possible at this time; however, EPA proposes that, in addition to any specified exposure limits, steps should be taken to preclude the occurrence of the "RF hearing" effect. Exposure levels should be limited on a case-by-case basis.

5. Exposure Parameters: A knowledge of the maximum values of electric and magnetic field strengths is required to fully assess the corresponding energy absorption rates in the body for nearfield and reflective exposure conditions. For sufficiently short wavelengths in the vicinity of most sources, it is adequate to determine the maximum possible electric or magnetic field strength to ensure that the undetermined magnetic or electric field strength will not exceed the limitations specified in the guidance. Thus, for frequencies greater than 30 MHz under standing wave conditions where the direction of propagation of the wavefront is perpendicular to a reflective surface, the distance separating maximum electric and associated magnetic fields will not exceed 2.5 meters. In many cases, this distance is small enough to assume that measurements which determine the maximum electric or magnetic field in a region whose dimensions are approximately one-quarter of a wavelength at the exposure frequency are sufficient to specify the maximum value of the corresponding magnetic or electric field strength. This is only true, however, when it can be established that a standing wave exists by finding repeating maximum values in either of the field quantities in the region of interest. For frequencies between 10 kHz and 30 MHz, measurement of one field does not necessarily allow prediction of the other because of the longer wavelengths, and both electric and magnetic field strengths must be measured.

Under Options 1–3, EPA proposes that the RF radiation exposure limits in this Guidance should be expressed in three alternative ways: (1) Either or both RMS electric or magnetic field strength, (2) mean squared field strengths, and (3) average plane-wave equivalent power densities. These alternative measures would allow ease of implementation since existing commercial broadband instrumentation is designed to measure one or more of these field parameters. The use of power density for specifying RF radiation exposure over the entire frequency range is inappropriate and is

technically incorrect for certain conditions such as reflective environments and non-planar wavefronts. Because of these considerations, any Guidance would be expressed in power density for frequencies below 30 MHz only for convenience in relating to other standards.

A significant question remains as to how close to conducting objects exposure field intensity measurements should be made. Variations in size and shape of instruments can lead to differences in measured values. These differences in measured values arise typically from capacitive coupling between the probe and nearby objects. This suggests the need for defining a minimum distance for such measurements. It is recognized that for measurements of leakage fields specified in certain consumer electronic product performance standards, shorter distances may be used if the instrument is designed for a specific device application. This is, for example, the case for microwave ovens. The ANSI has recommended a minimum 5 cm measurement distance for determining compliance with its standard (17). However, in the case of general environmental RF measurements, a minimum distance of 10 cm between the surface of conducting objects or radiating devices and the nearest part of an active element comprising a field measurement probe is preferable to reduce capacitive coupling effects between small measurement probes and the local environment (60, 61). Employment of larger distances may be advisable in the interest of further minimizing this factor.

6. Partial-Body and Whole-Body Exposures: In the general environment, it is impractical to distinguish between partial-body and whole-body exposures; therefore, EPA proposes that Guidance limits apply to all exposures.

7. Mixed Frequency Fields: For exposures to mixed frequency fields, the sum of the squares of the fractions of the field strength limits or the sum of the fractions of the power density limits, as appropriate, contributed by each frequency must not exceed unity.

8. Exclusions: EPA proposes to exclude from consideration occupational exposures, exposures of patients due to prescribed medical treatment or procedures using RF fields, and exposures originating from consumer electronic products. Regulating occupational exposures is within the purview of OSHA although EPA could issue occupational guidance in a separate action, if there is a need.

Environmental guidance should not apply to intentional exposure of patients. Emissions from consumer electronic products could be controlled through product performance standards. EPA, therefore, does not propose to apply any Federal Guidance for environmental exposures to such sources, but, because of increased development and use of new technologies, the Agency seeks comments and information on consumer electronic products such as portable radio communications equipment.

9. Implementation: If any Federal Guidance is adopted, EPA will work closely with other Federal Agencies in the development of implementation programs. The EPA considers the following issues to be important and seeks comments on matters related to the implementation of Federal Radiation

Guidance, if adopted.

a. Implementing agencies: Federal agencies would be responsible for implementing and complying with Guidance recommended by EPA and signed by the President. EPA proposes that each agency should: (1) Take whatever actions are necessary to protect the public health, (2) ensure that RF radiation exposure of the public due to activities under their jurisdiction conforms to the specified limits, (3) implement Guidance in a timely fashion and consult with EPA on appropriate timetables, (4) rely on EPA technical expertise and advice by cooperating with EPA in the development and application of programs and techniques for evaluating RF radiation exposure in the environment, (5) apply state-of-theart or best practical measurement technologies in compliance measurement programs, as determined by consultation with EPA, and (6) establish procedures to notify workers if their exposures in the workplace exceed public exposure limits.

b. EPA: To ensure efficient and effective compliance with Guidance, EPA is proposing to establish programs and develop capabilities necessary to assist Federal agencies in their implementation efforts. EPA would: (1) provide technical advice and assistance to implementing agencies to ensure cost effective and timely compliance with exposure guidelines, (2) establish within the Office of Radiation Programs the capabilities to develop measurement techniques and instrumentation systems required to monitor environmental RF radiation exposures and to prepare to assist Federal agencies in their implementation and compliance efforts, (3) cooperate with other Federal agencies by providing review of

compliance programs, (4) conduct reviews and inspections necessary to monitor compliance with Federal Guidance, (5) institute review of Guidance on at least a five-year cycle, (6) continue its environmental monitoring and assessment program to assure that data on population exposures, environmental levels, and sources is well-characterized and current for use by other agencies, (7) continue to evaluate health effects research on RF electromagnetic radiation from environmental sources to provide information to be used in the five-year review of the Guidance.

c. Intent: The practice of prudent radiation protection requires that sincere efforts be taken to maintain population exposures at levels as low as reasonably achieveable. Implementation programs, activities, and decisions should focus on the intent to protect

public health.

VII. Estimated Impact of these Proposals

A. Introduction

As discussed in Part IX, C of this Notice, the development of Federal Radiation Protection Guidance does not require a Regulatory Impact Analysis. but the Agency has investigated the potential impact of this proposed Guidance on RF-emitting sources. The results of field studies have shown broadcast sources, particularly FM radio stations, to be the most likely sources affected by this proposed Guidance. Greatest emphasis was, thus, given to analyzing impacts on the broadcasting industry, and the results of the engineering and cost analyses are described, respectively, in the following two reports: (1) An Engineering Assessment of the Potential Impact of Federal Radiation Protection Guidance on the AM, FM, and TV Broadcast Services (27), and (2) An Estimate of the Potential Costs of Guidelines Limiting Public Exposure to Radiofrequency Radiation from Broadcast Sources (28).

B. Economic Impacts

1. Impacts on the Broadcast Services

The estimated costs to society, to the broadcast industry, and to a hypothetical average firm associated with identifying field intensities and complying with each of the proposed regulatory options are given in Tables 3, 4, and 5 (28). Background information was not sufficient to permit development of cost estimates for the nonregulatory option, Option 4. [See also the discussion of benefits in Section 3 below.]

The cost estimates were derived by assuming that all stations will have to conduct an initial engineering survey of their emitted field intensities to determine whether they are in compliance with the Guidance. For FM and TV stations, a variety of corrective measures or mitigation strategies were used to compute costs. Fencing the area around the perimeter of an AM tower was considered as the only corrective measure to be taken by AM stations. It is possible that stations applying the same type of mitigation strategy could incur different costs because of likely variations between stations for factors such as equipment configuration, location, market, competition, power requirements, land ownership, and for AM stations, the presence and extent of fencing. Such variation was assumed in the cost analyses and is reflected in the three costs scenarios-low, medium, and high-shown in Tables 3, 4, and 5. Exact costs will depend on the mitigation method ultimately used by each station. It was also assumed that no station could use the posting of warning signs as the means of complying with any Guidance level.

Guidance implementation programs and procedures may ultimately not require an engineering survey or may not prohibit posting in all cases. Use of these two assumptions, therefore, means that costs of compliance may be overestimated. Allowing posting of FM stations can reduce the costs to FM broadcasters under Option 1 by as much as 20 percent. In Table 3, under the medium cost scenario for Option 1, the costs of engineering surveys account for about 25 percent of the total costs of compliance across all broadcast services. The engineering survey costs become a proportionally larger component of total costs in the less stringent Options 2 and 3.

Under the medium cost scenario, the number of sites likely to be affected

under each proposed regulatory option is about:

Service	Option 1	Option 2	Option 3		
AM	2,995	1,034	946		
FM	1,160	752 30	188		
Total	4,215	1,816	1,136		

It was assumed that 33 percent of AM stations already have existing fencing adequate for compliance. The figures above exclude building-mounted FM towers. In the United States, there are approximately 4,600 AM stations, 4,400 FM stations, and 1,100 TV stations.

In 1984, EPA initiated an information collection request to 1,128 FM radio broadcast stations to determine the potential for public access in the immediate vicinity of antenna towers (27). The survey asked whether the antenna tower was fenced, how far fences were from towers, and for the distance to property boundaries to help us assess the feasibility of installing a fence to limit access to higher intensity fields. Installation of a fence may be one of the least costly possible mitigation measures. The response rate was approximately 52 percent. The responses indicate that, for FM stations, at least 12 percent of the FM stations that would be affected by Option 3 already have fences around their towers that limit public access. Thus, the costs of compliance are overestimated and represent the worst case situation. Also, approximately 75 percent of the FM stations potentially affected by the Option 3 control sufficient land near their towers to permit installation of fences to limit public access. Although we have not determined the compliance cost reduction implied by this finding, it is clear that for some FM stations further cost reductions will occur over those just discussed.

2. Impacts on Nonbroadcast Sources

Estimates of the impact of proposed Federal Guidance on nonbroadcast sources were performed using a data base prepared for EPA by the Electromagnetic Compatibility Analysis Center (ECAC), a DOD installation in Annapolis, Maryland (62).

Table 3.—An Estimate of the Total Present (Constant Dollar) Value of the Cost to Society-at-Large of Guidelines Limiting Public EXPOSURE TO RADIOFREQUENCY RADIATION FROM FM, AM, AND TV BROADCAST SOURCES FOR THE THREE PROPOSED REGULATORY OPTIONS

[Dollars in millions] 1

	FM component			AM component			TV component			Total society cost		
	Low	Medi- um	High	Low	Medi- um	High	Low	Medi- um	High	Low	Medi- um	High
Option 1 Option 2 Option 3	22.2 16.2 7.8	44.7 31.2 12.4	80.4 41.6 16.0	9.4 6.8 6.7	15.0 9.8 9.6	22.0 13.3 12.8	7.1 3.5 1.4	9.8 4.7 1.9	11.0 5.4 2.4	38.7 26.5 15.9	69.5 45.7 23.9	93.4 60.3 31.2

Costs couldn't be estimated for the nonregulatory option, Option 4. See Section B.3, Benefits.

TABLE 4 .- AN ESTIMATE OF THE TOTAL PRESENT (CONSTANT DOLLAR) VALUE OF THE NET AFTER TAX COST TO THE BROADCAST INDUSTRY OF GUIDELINES LIMITING PUBLIC EXPOSURE TO RADIOFREQUENCY RADIATION FROM FM, AM, AND TV BROADCAST SOURCES FOR THE THREE PROPOSED REGULATORY OPTIONS

[Dollars in millions] 1

AND SHOULD BE SH	FN	FM component		AM component			TV component			Total society cost		
	Low	Medi- um	High	Low	Medi- um	High	Low	Medi- um	High	Low	Medi- um	High
Option 1 Option 2 Option 3	10,9 8.0 4.0	21.7 15.2 6.4	29.2 20.3 8.2	4.8 3.6 3.6	7.6 5.2 5.1	11.0 6.9 6.7	3.4 1.7 0.8	4.7 2.3 1.0	5.4 2.7 1.3	19.1 13.4 8.4	34.0 22.7 12.4	45.5 29.5 16.2

¹ Costs to the industry are the combined costs for all the firms in the industry. See Table 4 for an explanation of the derivation of firm costs. Costs could not be estimated for the nonregulatory option, Option 4. See Section B.3, Benefits.

TABLE 5 .- AN ESTIMATE OF THE POTENTIAL NET AFTER-TAX PRESENT VALUE COST TO THE HYPOTHETICAL AVERAGE BROADCAST STATION OF GUIDELINES LIMITING PUBLIC EXPOSURE TO RADIOFREQUENCY RADIATION FROM FM, AM, AND TV BROADCAST SOURCES FOR THE THREE PROPOSED REGULATORY OPTIONS

[Dollars in thousands]

	FM ¹			AM ²			TV 5		
	Low	Med	High	Low	Med	High	Low	Med	High
Option 1 Option 2 Option 3	7.5 7.4 6.4	16.1 15.8 13.6	22.0 21.4 18.3	1.4 1.3 1.3	2.0 1.9 1.8	2.6 2.4 2.4	45.6 33.8 23.1	63.7 45.9 30.8	70.3 50.6 34.0

¹ After-tax present value cost to FM stations based upon a hypothetical average FM station with pre-tax net operating income of \$139,400.
² After-tax present value cost to AM stations based upon a hypothetical average AM station with pre-tax net operating income of \$103,850.
³ After-tax present value cost of TV stations based upon a hypothetical average TV station with pre-tax net operating income of \$2,380,000.

Nonbroadcast sources, such as radars and satellite communications systems, were evaluated in terms of the numbers of sources likely to be affected by the proposed Guidance. This analysis was conducted by examining theoretically calculated field intensities near U.S. government transmitting installations for which frequency assignment records are maintained by the ECAC. No cost analyses could be performed, however, because the frequency assignment records used for site identification could not be used to identify individual systems to which Guidance implementation costs could be assigned. Also, development of cost estimates would be difficult because of the diverse characteristics of the different nonbroadcast emitting sources and the unavailability of cost data for much of the sophisticated military equipment. It was estimated, however, that the number of U.S. government installations that would be affected by any of the proposed recommended exposure limits

would be small in comparison to the total number of installations. The number of sites was derived by using near-field calculation techniques and conservative assumptions about sidelobe radiation properties of the transmitting antenna radiation patterns and by assuming a 100 percent duty cycle for shortwave (3-30 MHz) communication stations, i.e., they transmit continuously. At a distance of 100 meters from a source, the number of sites projected to exceed the levels under consideration in Option 1 is 164. When more realistic assumptions are made about side-lobe radiation and typical operational duty cycles for shortwave communication stations, the total number of sites predicted to exceed the Option 1 level drops to 56. The number of sites predicted to be in excess of levels under Options 2 and 3 would be smaller. The methods and results for analyses of nonbroadcast sources are discussed in the ECAC report (62).

3. Benefits

Establishing Federal Guidance to limit public exposure to RF radiation would also result in economic benefits for which EPA has not been able to assign monetary values. This information is based on review of comments and correspondence to the Agency from industry and governmental agencies at the Federal, state, and local levels. These benefits relate to a presumed reduction in costs currently incurred in the public and private sectors by, for example, litigation, inconsistent local regulations, local regulatory development and review, Environmental Impact Statement (EIS) development, and bans on installation of or modifications to communication systems. Such costs for industry are estimated to run to several million dollars per year but proprietary cost data have not been made available to EPA by industry. Similar costs may also be incurred by local governments involved in litigation, siting actions, or regulatory development. And, these costs might represent the costs to industry and society associated with not establishing Federal Guidance, the fourth and nonregulatory option proposed in this Notice. It is projected that the costs of compliance with Federal Guidance will, thus, be partially offset by the savings realized by reductions in the costs just mentioned.

Various techniques and approaches could be used to bring given stations into compliance with any particular Guidance level, if adopted. These include, but are not limited to, installing new antennas, changing the design or

configuration of existing antennas, limiting shared use of broadcast towers in densely populated areas, fencing, and posting. Development, sales, and application of such techniques could benefit certain sectors within the broadcasting industry (especially for antenna-related techniques) or other commercial and business interests, thereby, partially offsetting the overall

costs of compliance.

Depending on the exposure limit ultimately selected, if any, compliance with Guidance could reduce the potential for "blanketing," particularly in the FM broadcast service. Blanketing refers to the delivery of intense radio signals within a region of an AM or FM broadcast station that are so strong as to cause unacceptable signal discrimination in typical radio receivers, resulting in interference with reception of stations operating at other frequencies. Blanketing is regulated by the FCC for AM stations in its Rules and Regulations, Volume 3, Part 73, Radio Broadcast Services, Section 73.24 and for FM stations in Section 73.318.

VIII. Public Hearings

A public hearing will be held in Washington, D.C. for the purpose of receiving comments on these proposed recommendations. The specific date, location, and arrangements will be announced in a later Federal Register

IX. Miscellaneous Information

A. Background Reports

Development of this Notice required consideration of the biological effects of RF fields: the RF radiation environment in terms of environmental levels, public exposure, and RF emitting sources; and the potential impact, including economic impacts, that the proposed recommendations might have on affected RF sources and users of the electromagnetic spectrum. Several reports summarize our review and evaluation of these issues: (1) The Radiofrequency Radiation Environment: Environmental Exposure Levels and RF Radiation Emitting Sources (26), (2) An Engineering Assessment of the Potential Impact of Federal Radiation Guidance on the AM, FM, and TV Broadcast Services (27), (3) An Estimate of the Potential Costs of Guidelines Limiting Public Exposure to Radiation from Broadcast Sources (28), and (4) Biological Effects of Radiofrequency Radiation (25).

Information on how to obtain single copies of these reports is given under ADDRESSES in this Notice. The reports can also be purchased from the National Technical Information Service (NTIS). 5285 Port Royal Road, Springfield, Virginia 22161; requestors should cite the NTIS accession numbers given in the list of references in this Notice.

A copy of each of the background reports is available for inspection at EPA's Central Docket Section (see ADDRESSES) and at the library in each of the 10 EPA regional offices:

Region 1, JFK Federal Building, Room E-121, Boston, Massachusetts 02203, (Tel. (617) 223-5791);

Region 2, 26 Federal Plaza, Room 734, New York, New York 10278 (Tel. (212) 264-2881);

Region 3, 841 Chestnut Street, Philadelphia, Pennsylvania 19107. (Tel. (215) 597-0580);

Region 4, 345 Courtland Street, NE., Room G-6, Atlanta, Georgia 30365-2401, (Tel. (404) 881-4216);

Region 5, 230 S. Dearborn Street, Room 1670, Chicago, Illinois 60604, (Tel. (312) 353-2022);

Region 6, 1201 Elm Street, Room 2776, Dallas, Texas 75270 (Tel. (214) 767-

Region 7, 726 Minnesota Avenue, Room L-10, Kansas City, Kansas 66101, (Tel. (913) 236-2828);

Region 8, Radiation Program Office (in lieu of library), 999 18th Street, Suite 215, Denver, Colorado 80202, [Tel. (303) 293-1444);

Region 9, 215 Fremont Street, 6th Floor. San Francisco, California 94105, (Tel. (415) 974-8076);

Region 10, 1200 Sixth Avenue, 12th Floor, Seattle, Washington 98101, [Tel. (206) 442-1289).

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 (Public Law 96-511) requires that the Office of Management and Budget (OMB) review reporting and recordkeeping requirements that constitute "information collection" as defined. This proposed Guidance does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980 U.S.C. 3501 et seg.

C. Regulatory Impact Analysis

Executive Order (E.O.) 12291, requires the preparation of a Regulatory Impact Analysis for major rules, defined by the Order as those likely to result in:

1. An annual adverse effect on the economy of \$100 million or more;

2. A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

3. Significant adverse effects on competition, employment, investment, productivity, innovation, or on the

ability of United States-based enterprises to compete with foreignbased enterprises in domestic or export

EPA has determined that this proposed Guidance does not meet the definition of a major rule under E.O. 12291, and thus, a Regulatory Impact Analysis has not been prepared.

D. Regulatory Flexibility Certification

EPA recommendations to the President for radiation guidance are not subject to the requirements of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b) for analysis of economic effects on small business or other entities; therefore, a Regulatory Flexibility Analysis is not required. Nevertheless, the Agency has examined the potential economic impact posed by each of the proposed regulatory options, as discussed in Section VII above [27, 28). The Small Business Administration defines a nonmanufacturing small business as a firm with less than 100 employees. Under this criterion, we have determined that a significant number of broadcasting stations can be considered small businesses. The information in the cost study is, thus, useful for identifying the potential impact on small business of implementation of RF radiation exposure limits for each proposed option.

Although other Federal agencies will be responsible for implementing Guidance for radiofrequency radiation and for more fully determining the economic effects of implementation on small businesses, EPA is suggesting several ways that the impact of any Guidance on small businesses could be mitigated. These include: (1) Compliance could be phased in over a five-year period, with the larger stations phased in during the earlier years. This approach is similar to that used by EPA to estimate the potential costs of compliance. (2) Passive compliance measures could be allowed for small FM and TV stations, e.g., allowing the posting of warning signs in and around areas exceeding Guidance. (3) The cost estimates discussed in Section VII-B were derived by assuming an engineering survey of emitted field intensities would be mandatory in implementation programs. Stations could first be allowed to use analytical methods and models developed by EPA to determine whether a station is in compliance or whether an engineering survey would truly be necessary.

EPA is interested in more fully determining the impact of implementing Guidance on small business or other

entities and seeks comments on this subject. Information on how to provide written comments to EPA is contained in the section of this Notice entitled "ADDRESSES."

E. OMB Review

This Notice of Proposed
Recommendations was submitted to
OMB for review as required by
Executive Order 12291 and has received
their concurrence for publication.

Dated: June 12, 1986. Lee M. Thomas, Administrator.

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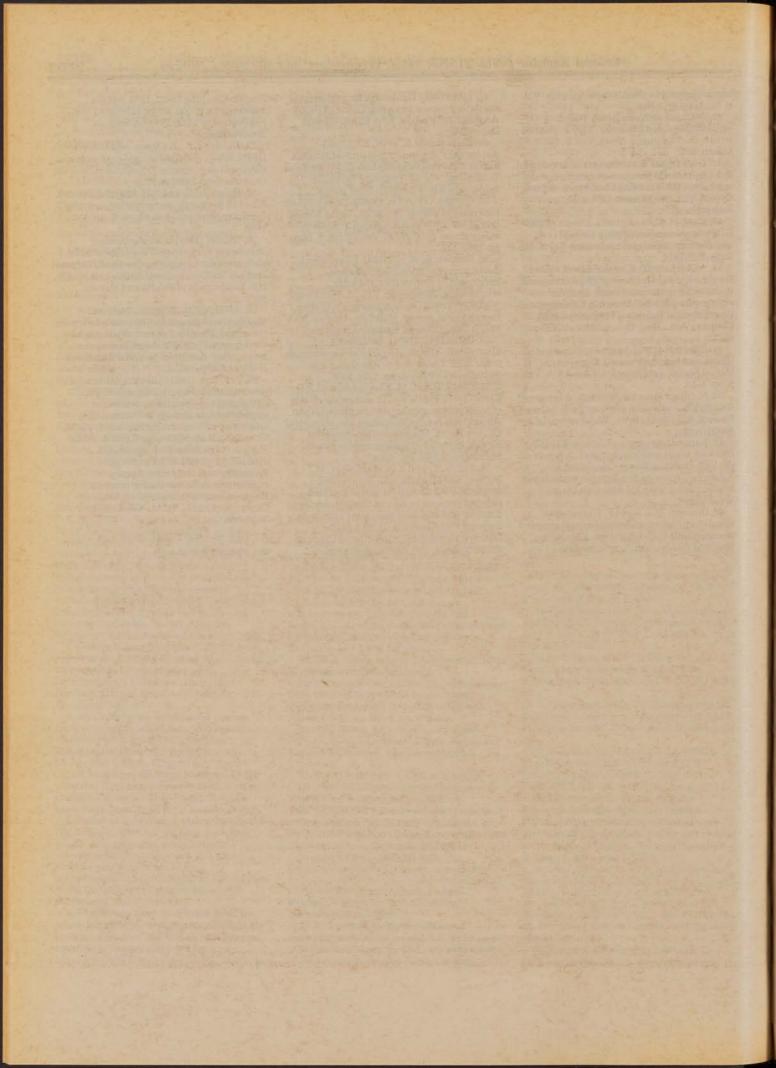
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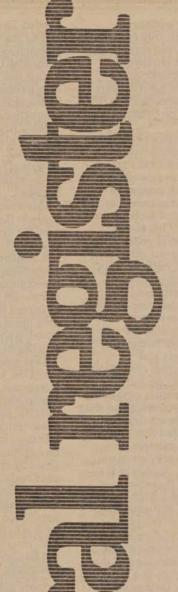
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[FR Doc. 86–13743 Filed 7–29.86; 8:45 am] BILLING CODE 6560-50-M





Wednesday July 30, 1986

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 331 Antacid Drug Products for Over-the-Counter Human Use; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 331

[Docket No. 85N-0049]

Antacid Drug Products for Over-the-Counter Human Use; Proposed Amendment of Antacid Monograph

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the final monograph for over-thecounter (OTC) antacid drug products to require that all antacid drug products contain the statement "Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician." FDA is issuing this notice of proposed rulemaking after considering public comments to a prior proposal (see the Federal Register of October 19, 1979; 44 FR 60328) and a citizen petition (Docket No. 82P-0360/CP) that requested additional labeling information to be included on OTC antacid drug products. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATE: Written comments or objections by September 29, 1986.

ADDRESS: Written comments or objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 4, 1974 (39 FR 19862), FDA issued a final monograph for OTC antacid drug products (21 CFR Part 331). Under § 331.30(d)(1), the labeling of OTC aluminum-containing antacid drug products is required to contain the drug interaction precaution "Do not take this product if you are presently taking a prescription antibiotic drug containing any form of tetracycline." In the Federal Register of October 19, 1979 (44 FR 60328), the agency proposed to amend the antacid monograph to require that this drug interaction precaution also be included on the labeling of antacid drug products containing calcium or magnesium. The proposed amendment would have also

required the following additional statement as part of the drug interaction precaution: "If you are not sure whether or not you are taking a tetracycline product, contact your physician or pharmacist." Interested persons were invited to file written comments to the proposed amendment on or before December 18, 1979.

In response to the notice of proposed rulemaking, five manufacturers, one trade association, one citizen's group, and one pharmaceutical association submitted comments. A number of the comments questioned the necessity and desirability of the second statement of the proposed warning. One comment questioned FDA's general policy with respect to OTC drug-prescription drug interaction precaution statements, in particular whether such statements should appear in prescription labeling rather than OTC drug labeling. Another comment urged that the proposed warning be limited to instances involving concurrent (simultaneous) ingestion of the antacids and tetracycline. One comment concurred with the proposed warning, but suggested the FDA consider expanding the warning to include prescription drug products other than tetracycline, or broadening it to include other products containing aluminum, calcium, or magnesium. Copies of the comments received are on public display in the Dockets Management Branch.

On November 15, 1982, FDA received a petition (Docket No. 82P-0360/CP) requesting, among other things, that the labeling of OTC antacid drug products include a precaution concerning the interaction between antacids and the prescription drug digoxin. In a letter dated August 23, 1983, the agency responded to the petition and stated that FDA would initiate the necessary action to implement the petitioner's request with respect to the drug interaction precaution.

After considering the comments to the October 19, 1979 proposed rule (44 FR 60328) and the petition received on November 15, 1982 (Docket No. 82P-0360/CP), the agency believes it is necessary to clarify its policy with respect to drug interaction precaution statements in the labeling of OTC drug products.

The agency's general approach to drug interaction labeling on OTC drug products was discussed in the Federal Register of June 4, 1974 (39 FR 19880). In the interest of providing fully informative labeling to the consumer, the agency stated "that the proper way to handle possible drug interactions is to require that the labeling [of OTC drug products] include a separate section

headed 'Drug Interaction Precautions,' stating the specific or general interaction problem involved with that particular OTC drug. . . . The same format will be used for other specific drug interactions found to exist in other monographs. Where known drug interactions exist but are not limited to a specific drug, the precaution statement shall be phrased in terms of general drug categories. . . .' The agency has been operating under this general policy since it was stated in the June 4, 1974 Federal Register.

However, in light of the comments made to the October 19, 1979 proposed rule, the agency believes it is necessary to expand its policy as follows:

1. In general, the agency believes that when an interaction between a prescription drug and an OTC drug is significant enough to be included in the approved labeling of the prescription drug product, a similar corresponding warning should be included in the labeling of the OTC drug product.

This general policy may not apply when the known prescription-OTC drug interaction cited in the prescription drug labeling affects only a limited portion of the total population taking the prescription drug. For example, the labeling for the prescription drug dexamethasone includes a statement advising that aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia. Conceivably, only a small subset of the population taking dexamethasone would have a hypoprothrombinemic condition and, therefore, the label warning may not be necessary on OTC aspirincontaining drug products.

2. Consistent with the June 4, 1974
Federal Register statements, in those cases where the known interactions are not limited to specific drugs and involve numerous drugs or entire drug categories, the statement would be phrased in terms of general drug categories. For example, if a significant number of prescription drugs are known to interact with an OTC drug, the interaction warning may need to be a general "prescription drug" warning rather than a listing of all possible prescription drugs likely to cause interactions.

3. Where interactions are known to exist between OTC drug products and are recognized as being significant, all of the OTC drug products involved should include the drug interaction precaution.

In the case of antacid drug products, the interaction between aluminum, calcium, or magnesium antacids and tetracycline is the most frequently reported. However, the agency is aware

of data in the literature indicating that the entire class of antacides, due to pHrelated and other mechanisms, interacts with a number of other drugs (Refs. 1 through 6). Many of the interactions result from elevation of the pH of the stomach contents produced by the antacids, which may in turn affect the rate of absorption of a number of drugs. In some cases the interaction may be beneficial, i.e., the drug may be absorbed faster and get to the site of action quicker. For example, the rate of absorption of salicylates, indomethacin, naproxen, pseudoephedrine, sulfadiazine, and levodopa is increased by elevated gastric pH.

In other cases, the rate of absorption may be delayed, thereby reducing efficacy of the drug. For example, the efficacy of tetracycline, digoxin. phenytoin, chlorpromazine, and isoniazid is reduced because of reduced absorption of the drugs. Aluminum hydroxide delays gastric emptying, thereby slowing the rate of absorption of indomethacin, dicumarol, isoniazid, barbiturates, and some benzodiazepines. In addition, aluminum hydroxide can adsorb and decrease the bioavailability of propranolol, antimuscarinic drugs, digoxin, tetracyclines, chlorpromazine, and sulfadiazine. Likewise, magnesium trisilicate interferes with the bioavailability of digoxin, certain benzodiazepines, phenothiazines, and antimuscarinic drugs. Antacids that increase urinary pH can delay the elimination and elevate the blood levels of quinidine and amphetamines.

Because of the number of significant interactions that can occur between antacids and prescription drugs, the agency is proposing the following drug interaction precaution for inclusion in the labeling of all OTC antacid drug products: "Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician." This statement would replace the current drug interaction precaution statement required by 21 CFR 331.30(d)(1). The statement proposed here would also replace the wording proposed in the Federal Register of October 19, 1979 (44 FR 60328). Elsewhere in this issue of the Federal Register, the agency is withdrawing the proposed rule of October 19, 1979.

In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and any applicable OTC drug regulations will give manufacturers the option of using either the word "physician" or the word "doctor." This document proposes that that option be added to the final monograph for OTC antacid drug products.

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Because this proposal relates only to warnings for OTC antacid drug products, the changes in the "exclusivity" policy that were recently published in the Federal Register of May 1, 1986 (51 FR 16258) do not apply to this document.

The agency advises that any final rule resulting from this proposed rule will be effective 12 months after its date of publication in the Federal Register. On or after that date, OTC drug products that are not in compliance may not be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved new drug application (NDA). Further, any OTC drug products subject to the rule that are repackaged or relabeled after the effective date of the rule must be in compliance with the rule regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment

determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC antacid drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96-354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC antacid drug products is not expected to pose such an impact on small businesses. Therefore. the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC antacid drug products. Comments regarding the impact of this rulemaking on OTC antacid drug products should be accompanied by appropriate documentation.

The agency has determined under 21 CFR 25.24(c)(6) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before September 29, 1986, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments or objections. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 331

OTC drugs, Antacid drug products. Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 331 as follows:

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for Part 331 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 stat. 919 and 72 stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

2. In § 331.30 by revising paragraph (d) and adding new paragraph (h) to read as follows:

§ 331.30 Labeling of antacid products.

(d) Drug interaction precautions. The labeling of the product contains the following statement under the heading "Drug Interaction Precautions":
"Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician."

(h) The word "doctor" may be substituted for the word "physician" in any of the labeling statements in this section.

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Dated: May 3, 1986.
Frank E. Young,
Commissioner of Food and Drugs.
[FR Doc. 86–17038 Filed 7–29–86; 8:45 am]
BILLING CODE 4180–01–M

21 CFR Part 331

[Docket No. 79N-0152]

Antacid Drug Products for Over-the-Counter Human Use; Withdrawal of Proposed Rule

AGENCY: Food and Drug Administration.
ACTION: Withdrawal of proposed rule.

SUMMARY: The Food and Drug
Administration (FDA) is withdrawing a
proposed rule that would have required
over-the-counter (OTC) antacid drug
products containing calcium and
magnesium to contain a precautionary
statement. Elsewhere in this issue of the
Federal Register, FDA is proposing a
revised drug interaction precaution for
all OTC antacid drug products. That
proposal supersedes the proposal being
withdrawn.

EFFECTIVE DATE: July 30, 1986.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 19, 1979 (44 FR 60328), FDA published a proposal to amend the monograph for OTC antacid drug products (21 CFR Part 331) to require a tetracycline drug interaction precaution statement on the labeling of calcium- and magnesium-containing OTC antacid drug products. The statement previously had been required only for aluminum-containing OTC antacid drug products. Elsewhere in this issue of the Federal Register, the agency is proposing an amendment to the monograph for OTC antacid drug products to require a prescription drug interaction precaution for all OTC antacid drug products. The new proposal supersedes the October 19, 1979 proposal, which is being withdrawn.

List of Subjects in 21 CFR Part 331

OTC drugs; Antacid drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)], under 21 CFR 5.11, and under 21 CFR 10.40(c), the proposed rule published in the Federal Register of October 19, 1979 (44 FR 60328) is withdrawn effective July 30, 1986.

Dated: May 3, 1986.
Frank E. Young,
Commissioner of Food and Drugs.
[FR Doc. 88–17039 Filed 7–29–86; 8:45 a.m.]
BILLING CODE 4160–01–M



Wednesday July 30, 1986

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 348 and 358

External Analgesic Drug Products for Over-the-Counter Human Use; Amendment to Tentative Final Monograph and Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Further Notice of Proposed Rulemaking and Notice of Proposed Rulemaking



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration 21 CFR Part 358

[Docket No. 82N-0214]

Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration.
ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which overthe-counter (OTC) dandruff, seborrheic dermatitis, and psoriasis drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by September 29, 1986. New data by July 30, 1987. Comments on the new data by September 30, 1987. These dates are consistent with the time periods specified in the agency's revised procedural regulations for reviewing and classifying OTC drugs (21 CFR 330.10). Written comments on the agency's economic impact determination by November 28, 1986.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 3, 1982 (47 FR 54646), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC dandruff, seborrheic determatitis, and psoriasis drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous

External Drug Products (Miscellaneous External Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these drug classes. Interested persons were invited to submit comments by March 3, 1983. Reply comments in response to comments filed in the initial comment period could be submitted by April 4, 1983.

In a notice published in the Federal Register of February 8, 1983 (48 FR 5762), the agency advised that it had extended the comment period until April 4, 1983, and the reply comment period to May 4, 1983, on the advance notice of proposed rulemaking for OTC dandruff, seborrheic dermatitis, and psoriasis drug products to allow for consideration of additional data and information.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA—305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

In response to the advance notice of proposed rulemaking, 11 manufacturers, 4 trade associations, 6 universities and foundations, and 5 health professionals submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

In order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10), the present document is designated as a "tentative final monograph." Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) to establish Subpart H of Part 358 (21 CFR Part 358 Subpart H), FDA states for the first time its position on the establishment of a monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products.

This proposals constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC dandruff, seborrheic dermatitis, and psoriasis drug products as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications

are reflected in the following summary of the comments and FDA's responses to them.

The OTC procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded). "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set

for removal of that condition from OTC

drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the Federal Register of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

I. The Agency's Tentative Conclusions on the Comments

A. General Comments.

 One comment urged that the agency recognize the legal status of the monographs issued under the OTC drug review as interpretive rather than

substantive regulations.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the Federal Register of May 11, 1972 (37 FR 9464) and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the Federal Register of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated there. Subsequent court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., National Nutritional Foods Association v. Weinberger, 512 F.2d 688, 696-98 (2d Cir. 1975) and National Association of Pharmaceutical Manufacturers v. FDA, 487 F. Supp. 412 (S.D.N.Y., 1980), aff'd, 637 F.2d 887 (2d Cir. 1981).

2. Noting the Panel's discussion of the microbiology of dandruff and the Panel's conclusion that there is not a definite correlation between the presence of the yeast *Pityrosporum ovale (P. Ovale)* and the development of dandruff (47 FR 54653), one comment cited four articles (Refs. 1 through 4) which were not available to the Panel and which add additional information for consideration.

The agency has reviewed the articles and determined that they offer no reason for the agency to disagree with the Panel's conclusion. Imokawa, Shimizo, and Okamoto (Ref. 1) reported that the use of zinc pyrithione produced a decrease in *P. ovale* corresponding to a reduction in dandruff, but that in the absence of treatment, dandruff returned even though the reduction in *P. ovale* persisted.

Idson (Ref. 2) states that "antidandruff agents owe their success to further qualities than only antimicrobial properties." Aron-Brunetiere, Dompmartin, and Drouhet (Ref. 3) reported that while their study would seem to establish a causal relationship between fungal infestation and dandruff, their results were not conclusive.

Belew (Ref. 4) theorized that there is a possible pathogenic sequence by which *P. ovale* and certain other yeasts could activate the body's immune system, but that the association of these microbial activators with scaling disorders in humans merits future research and consideration.

The agency concurs with the Panel that although there may be an association between the presence of P. ovale and dandruff, a definitive correlation has not been established. The Panel recommended that antimicrobial agents be judged on their own merit with respect to control of dandruff (47 FR 54654). The agency concurs. If such agents are shown in well-controlled double-blind clinical studies to be effective in controlling dandruff and are recognized as safe for OTC use, they will be placed in Category I. Such classification should not itself be taken as proof of any particular causal relationship in the treatment of dandruff, however, because an ingredient may be capable of acting in more than one therapeutic manner. For example, an antimicrobial might also have keratolytic or cytostatic properties. (See 47 FR 54654.)

References

(1) Imokawa, G., H. Shimizo, and K. Okamoto, "Antimicrobial Effect of Zinc Pyrithione," Journal of the Society of Cosmetic Chemists, 33:27–37, 1982.

(2) Idson, B., "Laboratory and Clinical Evaluation of Antidandruff Preparations," Journal of the Society of Cosmetic Chemists,

24:395-398, 1973.

(3) Aron-Brunetiere, R., D. Dompmartin, and E. Drouhet, "Treatment of Pityriasis Capitis (Dandruff) with Econazole Nitrate," Acta Dermatovener (Stockholm), 57:77–80, 1977.

- (4) Belew, P., "Sabouraud and Pivolta Were Right—Seborrheic Dermatitis is Microbial," Cosmetics and Toiletries, 96:25–28, 1981.
- 3. One comment contended that shampoo and other hair care products represented only to remove loose flakes of dandruff are cosmetics, not drugs, and are not subject to this rulemaking. Citing statements in two letters issued by the agency (Refs. 1 and 2) and FDA's Compliance Program Guidance Manual for fiscal year 1980 (Ref. 3), the comment contented that mere use of the word "dandruff" in the context of a truthful label claim that a cosmetic shampoo or other hair care product will "remove loose flakes of dandruff" from the hair cannot convert the product to a drug.

The comment requested that the monograph for OTC dandruff products be modified to include the statement "This monograph does not apply to a shampoo or other hair care product that is represented, insofar as dandruff is concerned, solely to clean the hair and scalp of loose dandruff scales or flakes. Such a product is subject to regulation only as a cosmetic and not a drug."

A reply comment disagreed strongly with the above comment, expressing the opinion that agency officials were incorrect in the cited letters which supported use of the term "dandruff" in cosmetic labeling. This reply comment stated that FDA's 1983 Compliance Program Guidance Manual (Ref. 4) "makes no reference to dandruff and may be properly considered as a revocation of the earlier comment." This comment pointed out that no medical authority has been cited to support the use of the term "dandruff" in cosmetic products.

A second reply comment restated and supported the original comment's arguments that although claims for the "prevention" or "control" of dandruff are drug claims, claims that merely refer to "washing away loose flakes of dandruff" are mere cosmetic claims. This reply comment went on to point out that the first reply comment cited no authority in disagreeing with the letters by agency officials (Refs. 1 and 2) cited in the original comment. This reply comment maintained that no change in agency position (Ref. 3) on the cosmetic/ drug status of the term "dandruff" was suggested or implied by the "silence" on the term "dandruff" in the 1983 manual.

The agency agrees with the original comment that the mere use of the word "dandruff" does not automatically render a shampoo or other hair care product subject to regulation as a drug. The Federal Food, Drug, and Cosmetic Act defines a "drug" as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . . (or) intended to affect the structure or any function of the body . . (See 21 U.S.C. 321(g)(1) (B) and (C).) A "cosmetic," on the other hand, is defined as an article intended to be "applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance." (See 21 U.S.C. 321(i)(1).) The product's intended use, therefore, determines whether it is a "drug," a "cosmetic," or both. This intended use may be inferred from the product's labeling, promotional material, advertising, and any other relevant factor. See, e.g., National Nutritional Foods Association v. Mathews, 557 F.2d

325, 334 (2d Cir. 1977). When the use of the term "dandruff" deals only with appearance and not with the treatment or prevention of the underlying disease condition, as in the context that a product removes loose flakes of dandruff or cleans the hair of dandruff flakes or scales, the product is cosmetic in nature. This position is clearly and correctly stated by the agency in the letters cited by the original comment (Refs. 1 and 2).

Any use of the term dandruff that would make or imply a claim for the prevention, control, or treatment of dandruff beyond the simple mechanical removal of flakes and scales would, of course, render the product a drug.

Examples of claims that would cause a hair care product to become a drug include terms such as "antidandruff," "dandruff control shampoo," "dandruff treatment," or "prevents dandruff." The agency further concludes that the differences between drug and cosmetic claims are sufficiently clear that the statement requested by the first comment is unnecessary.

References

(1) Letter from E. G. Seibert, FDA, October 29, 1980, in OTC Volume 16MTFM.

(2) Letter from R. C. Wetherell, Jr., FDA, to Senator J. K. Javits, May 10, 1979, in OTC Volume 16MTFM.

(3) FDA Compliance Program Guidance Manual, Program 7329.001, Chapter 29, Cosmetics, 1980, copy included in OTC Volume 16MTFM.

(4) FDA Compliance Program Guidance Manual, Program 7329.001, Chapter 29, Cosmetics, 1963, copy included in OTC Volume 16MTFM.

4. One comment stated that the Panel's recommended requirements on the drug uses of various ingredients should not establish requirements or inferences for cosmetic uses of the ingredients. The comment cited menthol, methyl salicylate, and captan as ingredients that are regularly used in cosmetics, but which lack sufficient evidence of effectiveness to permit their classification as Category I ingredients for control of dandruff.

The comment urged the agency to include a statement that the OTC drug monograph will "cover only the drug use of the active ingredients listed therein" and that "the concentration range, limitations, warnings, and directions established for these ingredients in the monograph will not apply to the use of the same ingredients in products intended soley as cosmetics." The comment pointed out that a similar statement was included in the preamble to the tentative final monograph for OTC skin protectant drug products,

published in the Federal Register of February 15, 1983 (48 FR 6820).

OTC drug rulemakings cover only the drug use of certain active ingredients. The concentration range, limitations, warnings, and directions established in an OTC drug monograph do not apply to the cosmetic use of ingredients, such as menthol, methyl salicylate, and captan when used in products labeled solely as cosmetics. However, if a product is intended for both drug and cosmetic use, it must conform to the requirements of the final OTC drug monograph.

The agency believes that the statement requested by the comment, i.e., that the monograph will "cover only the drug use of the active ingredients listed therein" is unnecessary because § 358.701(a) (Scope) and § 358.703 (Definitions) clearly limit the coverage of the monograph to drug products and do not apply to cosmetics. (See comment 3 above.)

In the preamble to the tentative final monograph for OTC skin protectant drug products, the agency proposed that the term "drug" be substituted for "agent" as a clarification of the scope and definition of a skin protectant (48 FR 6822 to 6823). Because the term "drug" has already been included in the scope and definition sections of the Panel's recommended monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products, no change is necessary in those sections of the present tentative final monograph.

B. Comments on Active Ingredients

5. Numerous comments objected to the Panel's Category III classification of coal tar preparations for use on the body. The comments noted that although the Panel was interested in long-term prospective studies in order to resolve theoretical concerns regarding the carcinogenic potential of coal tar products, it was clearly the Panel's intent for these preparations to remain available over-the-counter. Several comments also stated that data from 25year retrospective studies on the safety of coal tar were presented to the Panel, but that the Panel did not adequately consider these data in its final report. The comments stated that the results of these studies, which have now been published (Refs. 1 and 2), provide reassurance that the clinical use of coal tar does not significantly alter the frequency of neoplasms.

Several comments cited additional publications that were not available to the Panel as further support for the safety of coal tar preparations (Refs. 3 through 6). One comment noted that although one recent study (Ref. 7) showed an increase in cancer rates in

certain patients treated with coal tar, the study population was also receiving 8-methoxypsoralen photochemotherapy, which in itself may be a carcinogen or malignancy promoter.

One comment stated that the benefits of using coal tar in treating psoriasis far outweigh any theoretical risk or the risks associated with currently available alternative therapies. One comment suggested that any theoretical risks could be adequately handled by label warnings. The comment recommended labeling that would: (1) advise consumers to consult a physician every 6 months while using these products; and (2) advise consumers not to combine the use of products containing coal tar with other forms of therapy, such as ultraviolet radiation, unless directed by a physician.

Based on the available data and information, the agency concludes that coal tar preparations can be generally recognized as safe and effective for OTC use in controlling dandruff, seborrheic dermatitis, and psoriasis of the scalp or body.

As the Panel discussed in its report, it is well-established that coal tar contains substances that possess carcinogenic properties (47 FR 54657). Although there are reports in the literature regarding the development of neoplasms in patients who have had a history of coal tar use (Refs. 7 through 12), the reports are sporadic and are complicated by the fact that the patients were often exposed to multiple treatments. including ionizing radiation, arsenic, and ultraviolet radiation, as well as coal tar. The agency recognizes the difficulty in drawing definitive conclusions regarding coal tar from these studies.

Since the Panel completed its review of coal tar, two 25-year retrospective studies on coal tar use have been published in the literature (Refs. 1 and 2). One study included 260 patients with psoriasis who were hospitalized and treated with crude coal tar and ultraviolet radiation and who subsequently used coal tar preparations to control their psoriasis (Ref. 1). The other study included 305 patients with atopic dermatitis and neurodermatitis who were hospitalized and treated with coal tar and utltraviolet light (Ref. 2). The use of coal tar products after initial treatment varied in this study from none to daily use for 26 years. In both studies, groups were compared by examining multiple characteristics that may have affected eventual outcome. In neither study was the number of patients in whom skin cancer developed significantly different from the expected incidence for selected populations of the United States. Others have reported

similar results (Refs. 3 through 6).
Although none of these studies can be used to conclude definitively that the therapeutic use of coal tar is totally free of carcinogenic risk, they do provide adequate evidence that the risk, if it does exist, is relatively small. The agency also recognizes that the risks associated with coal tar use are less than the risks associated with alternative forms of psoriasis therapy.

The agency believes that the benefits to be derived from the use of coal tar outweigh the potential risks. Therefore, the agency is proposing that coal tar preparations be reclassified in Category I in this tentative final monograph. However, because the potential risks cannot be totally dismissed, the agency agrees with the one comment that the labeling of coal tar products should advise consumers not to use these products for prolonged periods of time without consulting a physician and not to use other forms of psoriasis therapy with coal tar unless directed by a doctor. Therefore, the following warnings are being proposed in the tentative final monograph: (1) "Do not use for prolonged periods without consulting a doctor." and (2) "Do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to do so by a doctor.

Although coal tar preparations are being proposed as Category I in this tentative final monograph, the agency advises that if new data become available demonstrating that use of coal tar preparations is associated with a significant risk of skin cancer, FDA will reexamine this classification in preparing the final monograph.

References

- (1) Pittelkow, M.R., et al., "Skin Cancer in Patients With Psoriasis Treated With Coal Tar," Archives of Dermatology, 117:465-468,
- (2) Marxgham, W.Z., et al., "Incidence of Skin Cancers In Patients With Atopic Dermatitis Treated With Coal Tar," Journal of the American Academy of Dermatology. 3:612-615, 1980.
- (3) Menter, A., and D.L. Cram, "The Goeckerman Regimen in Two Psoriasis Day Care Centers," Journal of the American Academy of Dermatology, 9:59-65, 1983.
- (4) Anderson, T.F., "Psoriasis," Medical Clinic of North America, 86:769-799, 1982.
- (5) Gotz, H., B. Deichmann, and M. Zabel, "Regarding the Question of latrogenic Carcinoma Prevention through the Use of Tar in Dermatology," Zietschrift fur Hautkrankheiten, 55:751-755, 1978.
- (6) Larko, O., and G. Swanbeck, "Is UVB Treatment of Psoriasis Safe? A Study of Extensively UVB-Treated Psoriasis Patients Compared with a Matched Control Group,"

- Acta Dermatologica-Venereologica, 62:507-
- (7) Stern, R.S., S. Zierler, and J.A. Parrish, "Skin Carcinoma In Patients With Psoriasis Treated With Topical Tar and Artificial Ultraviolet Radiation," Lancet, 1:732-735,
- (8) Rook, A.J., et al., "Squamous Epithelioma Possibly Induced By Therapeutic Application of Tar," *British Journal of* Cancer, 10:17-23, 1956.
- (9) Greither, A., C. Gisbertz, and H. Ippen, "Teerbehandlung und Krebs," Zeitschrift für Hautkrankheiten, 42:631-635, 1967.
- (10) Lagerholm, B., and E. Skog, "Squamous Cell Carcinoma In Psoriasis Vulgaris: Three Cases of Squamous Cell Carcinoma Developing in Psoriatic Lesions," Acta Dermato Venereologica, 48:128-136, 1968. (11) Denkin, W., et al., "Melanoma In a
- Patient Treated For Psoriasis," Southern Medical Journal, 71:732-733, 1978.
- (12) Kaaber, K., "Occurrence of Malignant Neoplasma in Patients With Atopic Dermatitis," Acta Dermato Venereologica, 56:445-447, 1976.
- 6. Two comments questioned the dosage range for coal tar solution in shampoos, One comment pointed out that coal tar solution is at most 20 percent coal tar USP, and that the Panel's recommended lower dosage limits of coal tar USP (0.5 percent) and coal tar solution (2.5 percent) reflect this relationship, but that this 5 to 1 ratio is not reflected in the upper dosage limit of 5 percent recommended by the Panel for both preparations. The comment suggested that the upper dosage limits be adjusted to reflect this relationship and recommended that 15 percent coal tar solution and 3 percent coal tar USP be used. The second comment stated that, at its 37th meeting, the Panel discussed and approved a number of marketed concentrations of coal tar solution shampoos including a 7.5 percent dosage, but that the advance notice of proposed rulemaking contains an upper limit of 5 percent coal tar solution. The comment asserted that the Panel intended to include the 7.5 percent coal tar solution in its recommendation for Category I dosages and requested that this dosage be included in the proposed rule.

The agency believes that the Panel based its concentration ranges for coal tar preparations on data submitted for marketed products and not on any particular relationship between coal tar and coal tar solution. Although the comment is correct that coal tar solution USP is at most 20 percent coal tar USP, the agency does not believe that the concentration ranges for coal tar and coal tar solutions should be based solely on this relationship. In determining the appropriate concentration limits for coal tar preparations, the agency has considered the comments filed by the

Joint Industry Coal Tar Committee (IICTC) (Ref. 1) and is proposing in comment 7 below to redefine the concentration ranges of coal tar preparations in terms of the relative coal tar content. These proposed revisions will also provide for the higher concentration coal tar solution product requested by the one comment.

- (1) Report of the Joint Industry Coal Tar Committee, Comment C00021, Docket No. 82N-0214, Dockets Management Branch.
- 7. One comment objected to the Panel's discussion of the chemistry of coal tar at 47 FR 54656. The comment stated that, while some recent references were cited, statements relating to descriptions of coal tar fractionization rely on old references even through more recent information was available to the Panel. The comment stated that the submission by The Proprietary Association (Ref. 1) that was presented to the Panel at its last meeting provided a more appropriate description of coal tar, but that this submission was not addressed by the Panel. Another comment also endorsed The Proprietary Association submission stating that submission included a proper definition of coal tar USP and its solutions, fractions, and extracts. The comment also provided information comparing its special coal tar extract to coal tar topical solution, USP, and contended that the two extracts have similar properties in spite of manufacturing differences.

A third comment submitted the interim report of the HCTC (Ref. 2) describing the industry's efforts in developing more definitive specifications for medicinal coal tar as opposed to tars used for other purposes. The comment suggested that medicinal coal tar be defined as the tar obtained as a byproduct during the destructive distillation bituminous coal at temperatures in the range of 900° C to 1100° C. The comment stated that specifying the carbonization temperature would insure a more uniform coal tar because the composition of the tar is dependent on the carbonization temperature used. The comment also noted the JICTC's intention to present its recommendations regarding coal tar standards to the USP as soon as its work is completed.

After reviewing the available data, the agency acknowledges that, due to the complex chemistry of coal tar and its extracts and distillates, specifications additional to those recommended by the Panel and those contained in the USP

XXI may be necessary for describing these products in the monograph.

Based on the JICTC report (Ref. 2), the agency believes that for proposes of the OTC drug monograph, coal tar should be defined as "the tar used for medicinal purposes that is obtained as a byproduct during the destructive distillation of bituminous coal at temperatures in the range of 900 °C to 1100 °C. It may be further processed using either extraction with alcohol and suitable dispersing agents and maceration times or fractional distillation with or without the use of suitable organic solvents. The concentration of the coal tar portion of the final product should be in a relative concentration range of 0.5 to 5 percent coal tar." The agency believes that this definition reflects the coal tar that is currently being used for medicinal purposes and will provide for sufficient flexibility in the marketing of coal tar products because coal tar solutions and coal tar extracts in final formulation are essentially similar in that they contain the same relative concentration of coal tar and exhibit little difference in therapeutic activity. The agency invites specific comments on these proposed coal tar specifications. The agency commends the industry's efforts in developing more definitive specifications and urges their continued involvement and cooperation in assuring adoption of more definitive specifications for inclusion in the USP.

References

- (1) Unpublished data, Comment C00020, Docket No. 82N-0214, Dockets Management Branch
- (2) Report of the Joint Industry Coal Tar Committee, Comment C00021, Docket No. 82N-0214, Dockets Management Branch.
- 8. One comment contended that 1 percent selenium sulfide is safe and effective for the treatment of seborrheic dermatitis of the scalp as well as for dandruff. The comment submitted a study in which 1 percent selenium sulfide shampoo was used by 10 patients with seborrheic dermatitis (Ref. 1). The comment stated that the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group and FDA recognized a 2.5-percent concentration of selenium sulfide as safe and effective for seborrheic dermatitis. (See the Federal Register of July 17, 1971; 36 FR 13286.) The comment also noted that the Panel clearly stated in its report that "ingredients effective in relieving the symptoms of dandruff will also relieve the symptoms of seborrheic dermatitis" (47 FR 54655).

The Panel placed a 1-percent concentration of selenium sulfide in

Category III for the OTC treatment of seborrheic dermatitis of the scalp because it was not aware of data to demonstrate that the 1 percent concentration effectively controls seborrheic dermatitis. However, the study by Jean et al. (Ref. 1) submitted by the comment demonstrates clinically significant improvement in 9 out of 10 patients with medium-severe to severe seborrheic dermatitis during the course of a 30-day treatment period. This study, designed as a safety study, demonstrated no adverse effects and no statistically significant increase in plasma and urinary levels of selenium and also demonstrated the effectiveness of 1 percent selenium sulfide in controlling seborrheic dermatitis.

In view of the results of this study the agency is proposing Category I status for 1 percent selenium sulfide for seborrheic dermatitis.

Reference

- (1) Jean, Y., et al., "Plasma Levels and Urinary Excretion of Selenium After Application of a 1% Selenium Sulfide Shampoo to Patients with Seborrheic Dermatitis," Selenium in Biology and Medicine, "Proceeding of the International Symposium 2nd, 1980," pp. 422–426, 1981.
- 9. One comment stated that the Panel, in making its recommendations on the safety and effectiveness of a 2- to 5percent sulfur preparation for the treatment of dandruff, based its conclusions on the interim report of an 8-week study (Ref. 1). The comment submitted the final report on that 8week study (Ref. 2) and pointed out that the results confirm that a 2- to 5-percent concentration of sulfur in a shampoo dosage form is superior to shampoo alone in the treatment of dandruff. The comment added that the final report contained the additional finding that 5 percent sulfur shampoo was statistically superior to 2 percent sulfur shampoo in the treatment of dandruff. The comment also asserted that the Panel in its discussion of the interim report on this study erroneously stated that corneccyte counts were made, when in fact, no corneocyte counts were performed in this study.

The agency acknowledges the erroneous mention of corneocyte counts in connection with the interim report on this study. The Panel concluded that sulfur is safe and effective in concentrations of 2 to 5 percent for OTC topical use for controlling dandruff. The final report (Ref. 2) further confirms the Panel's conclusions.

References

(1) Meltzer, N., Presentation at 42d Meeting of the Advisory Review Panel on

- Miscellaneous External Drug Products, November 7, 1980.
- (2) Rapaport, M., unpublished study IRSI208HCO880, Comment C0019, Docket No. 82N-0214, Dockets Management Branch.
- 10. Two comments asserted that the concentration ranges for pyrithione zinc recommended by the Panel in § 358.710 (e) and (f) must be related to specific product forms because as currently stated any of the concentrations could be used in a hairgroom or in a shampoo. The comments stated that it was clearly the Panel's intention that "... preparations containing 1 to 2 percent zinc pyrithione in a shampoo and 0.1 to 0.25 percent zinc pyrithione in a hairgroom are effective in controlling dandruff and seborrheic dermatitis" (47 FR 54666).

The comments requested that the concentration ranges for pyrithione zinc be clearly designated as specific product forms to avoid confusion.

The agency agrees that clarification of the monograph is necessary. The tentative final monograph designates the higher concentration range of pyrithione zinc for product formulations that are intended to be applied and then washed off after brief exposure and the lower concentration range for product formulations that are intended to remain on the skin or scalp.

11. One comment requested that the lower limit of the concentration range for pyrithione zinc in dandruff shampoos be changed from 1 percent to 0.95 percent. The comment pointed out that this slight adjustment in the minimum concentration would permit manufacturers to produce a single formulation for both United States and international markets. The comment explained that some countries, e.g., Germany, permit the sale of pyrithione zinc only at dosage levels of "less than one percent." To support its request, the comment submitted a 35-day clinical study of the effectiveness of a shampoo containing 0.95 percent pyrithione zinc (Ref. 1).

The data submitted by the comment show that the 0.95-percent pyrithione zinc shampoo formulation produced significant improvement in the patients' conditions as measured by degree of scaling and by corneocyte counts. In addition, the agency notes that the requested change in concentration is very slight, is not apt to cause any decrease in product effectiveness, and will allow for manufacturers to market a single product that could be sold both in the United States and in foreign markets. Therefore, the agency is proposing in this tentative final monograph that the lower limit of

pyrithione zinc be changed from 1.0 percent to 0.95 percent.

Reference

- (1) Unpublished study, Comment C0017, Docket No. 82N-0214, Docket Management Branch.
- 12. One comment questioned the validity of the Panel's conclusions that borate preparations are not safe for the treatment of dandruff and seborrheic dermatitis. The comment noted that products reviewed by the Panel contained only 0.5 percent boric acid or 0.47 percent sodium borate and expressed the opinion that the Panel based its conclusions on predetermined opinion without objectively evaluating literature findings or considering the concentrations of boric acid and sodium borate used in dandruff preparations.

The comment stated that the LD₅₀ in rats is over 3,100 milligrams per kilogram (mg/kg) for either boric acid or sodium borate. The comment called attention to a 2-year feeding study on rats and dogs by Weir and Fisher that apparently was not considered by the Panel (Ref. 1). The comment requested the agency to reevaluate the Panel's conclusions on the safety of boric acid and sodium borate.

The agency has reviewed all available data on borates including the reports of other OTC panels. The Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products, after studying the problem of borate absorption through vaginal tissue, concluded in both its report on OTC vaginal contraceptive drug products, published in the Federal Register of December 12. 1980 (45 FR 82014), and its report on OTC vaginal drug products, published in the Federal Register of October 13, 1983 (48 FR 46694), that boron compounds were safe for use in the vaginal area in concentrations of up to 1 percent as preservatives. (See 45 FR 82042 and 48 FR 46712.) The Advisory Review Panel on OTC Ophthalmic Drug Products concluded in this report, published in the Federal Register of May 6, 1980 (45 FR 30002), that borates were safe for use in infected eyes at up to 5 percent concentrations. (See 45 FR 30029.) The Advisory Review Panel on OTC Antimicrobial II Drug Products concluded in its report on OTC topical antifungal drug products, published in the Federal Register of March 23, 1982 (47 FR 12480), and in its report on OTC topical acne drug products, which was published the same day (47 FR 12430). that borates were safe for topical application at up to 5 percent concentrations. (See 47 FR 12528 and 47 FR 12452.)

Based on the above Panel reports as well as its own review of the data, the agency concludes that there is ample evidence to support the safety of up to 1 percent concentration of borates for OTC use in dandruff and seborrheic dermatitis preparations. Although the agency believes that the safety of borates in concentrations used in OTC dandruff and seborrheic dermatitis drug products (up to 1 percent) has been adequately demonstrated, the effectiveness of these compounds for the treatment of those conditions has not been demonstrated. Therefore, the agency concludes, that in concentrations of 1 percent or less, boric acid and sodium borate are considered Category II for effectiveness.

Reference

- (1) Weir, R.J., and R.S. Fisher, "Toxicologic Studies on Borax and Boric Acid," Toxicology and Applied Pharmacology, 23:351–364, 1972.
- 13. One comment requested that 0.25 to 1 percent hydrocortisone be reclassified as Category I for the treatment of seborrheic dermatitis. The comment asserted that data submitted to the Panel (Ref. 1) establish the safety and effectiveness of these concentrations of hydrocortisone in the treatment of seborrheic dermatitis.

The data referred to by the comment were initially submitted to the Miscellaneous External Panel, but were not reviewed by the Panel during the development of its report on OTC dandruff, seborrheic dermatitis, and psoriasis drug products. Subsequently, the agency has reviewed the data and concludes that these data, together with the conclusions of the NAS/NRC, Drug Efficacy Study Group, which were published in the Federal Register of April 28, 1971 (36 FR 7982), support the general recognition of the safety and effectiveness of hydrocortisone in providing temporary symptomatic relief of the inflammation and itching associated with seborrheic dermatitis and psoriasis.

Hydrocortisone has been shown to be beneficial in treating the redness and itching associated with a wide variety of dermatoses, and is classified as a Category I ingredient in the tentative final monograph for OTC external analgesic drug products that was published in the Federal Register of February 8, 1983 (48 FR 5852). In that tentative final monograph, the agency proposed that 0.25 to 0.5 percent hydrocortisone be generally recognized as safe and effective for OTC use in relieving the symptoms associated with a variety of dermatoses. Because the symptoms included in that rulemaking,

i.e., itching, irritation, and inflammation, are very similar to those associated with seborrheic dermatitis and psoriasis, the agency believes that it would be more approporiate to amend the tentative final monograph for OTC external analgesic drug products to add seborrheic dermatitis and psoriasis to the list of conditions for which hydrocortisone has been found to be safe and effective in providing symptomatic relief rather than to include hydrocortisone as an ingredient in the tentative final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products. In this way, the various conditions for which hydrocortisone is considered generally recognized as safe and effective for OTC use will be listed in one monograph.

Therefore, elsewhere in this issue of the Federal Register, the agency is proposing to amend the proposed rule for OTC external analgesic drug products to include seborrheic dermatitis and psoriasis as conditions for which hydrocortisone and hydrocortisone acetate have been found to be safe and effective in providing symptomatic relief. The agency notes that the dosage range for hydrocortisone requested by the comment exceeds that proposed for hydrocortisone in the tentative final monograph for OTC external analgesic drug products. The agency will consider the request that concentrations of hydrocortisone greater than 0.5 up to 1 percent be classified as Category I in developing a final monograph for OTC external analgesic drug products.

Reference

- (1) OTC Volumes 160061 to 160066, Docket No. 82N-0214, Dockets Management Branch.
- 14. One comment requested that the agency classify chloroxylenol in Category I for safety. The comment asserted that although the Miscellaneous External Panel concluded that there was a lack of subchronic data, the Advisory Review Panel on Antimicrobial II Drug Products, in its report on OTC topical antifungal drug products (47 FR 12535), considered such data and concluded that chloroxylenol is safe for OTC use as a topical antifungal in concentrations of up to 3.75 percent.

Although the Antimicrobial II Panel concluded that chloroxylenol was safe for short-term use (up to 13 weeks), it expressed concern over the effects that chronic administration of this drug may have on the liver (47 FR 12534). At this time, the agency is evaluating all available data on the safety of chloroxylenol under the rulemaking for

OTC topical antimicrobial drug products (Docket No. 75N-0183). The conclusions reached by the agency on the safety of topical chloroxylenol under that rulemaking will also apply to this rulemaking. Until the evaluation is completed, chloroxylenol will remain in Category III in this rulemaking for

safety

15. On comment requested that undecylenic acid moneothanolamide sulfosuccinate sodium salt be reclassified as Category I for safety in the treatment of dandruff and seborrheic dermatitis. The comment argued that because only one of the six toxicologic studies submitted on this compound was cited by the Panel, these safety data do not appear to have been fully considered (Refs. 1 through 6). The comment suggested that this may have been due to confusion resulting from the use of different trade names and trademarks to identify this same ingredient in different studies.

The comment further suggested that the Panel may have placed undue emphasis on this compound being an undecylenate preparation when it might well be described both chemically and functionally as a sulfosuccinate, a class of compounds widely used in skin contact products in the cosmetic industry. The comment pointed out that there was no evidence of treatmentrelated primary irritation or secondary sensitization in the efficacy studies submitted on this compound (Refs. 7 and

The comment added that this compound has been used in antidandruff shampoos in Europe and Canada for over 20 years and has been used in cosmetic shampoos in the United States with no reports of skin or eye irritation or any toxic reaction.

The agency has reviewed the six toxicologic studies cited by the comment. These studies include the following: (1) A 7-day rabbit eye irritation study in which no signs of irritation were shown using a 5-percent solution of this compound (Ref. 1); (2) a test of various concentrations of the compound from 0.39 to 50 percent for anesthetic effects on rabbit eyes; the results showed no anethesia was produced and that significant irritation occurred only at the 50 percent concentration (Ref. 2); (3) a guinea pig skin sensitization test by the Draize method which demonstrated that this compound is not a sensitizer (Ref. 3); (4) an acute oral toxicity test in rats which showed an LD50 greater than 10 grams per kilogram (g/kg) (Ref. 4); (5) an acute toxicity test by subcutaneous injection in mice which showed an LD50 greater than 2 g/kg (Ref. 6); (6) a subacute

dermal toxicity test in rabbits which showed mild to moderate skin irritation but no toxicity from application of up to 1.428 milliliters per kilogram (ml/kg) of a 50-percent concentration of undecylenic acid monoethanolamide sulfosuccinate sodium salt daily for 20 days (Ref. 5). In addition, a high dose (50-percent concentration) eye irritation study in nine rabbits produced only one corneal lesion that had not healed within 7 days. No iris lesions were produced (Ref. 9). In view of the above toxicity data and the long history of use of this compound in shampoo type products in this and other countries, the agency concludes that undecylenic acid monoethanolamide sulfosuccinate sodium salt is safe for topical use up to the 2-percent level recommended by the Panel.

The agency notes, however, that this compound, although it has been used in cosmetic shampoos, has never been marketed in this country for the treatment of dandruff, psoriasis, or seborrheic dermatitis, whereas another undecylenate salt, calcium undecylenate, has been marketed for the treatment of these conditions. Although effectiveness testing of this compound is currently underway (Ref. 10), this compound was classified as Category III by the Panel for the treatment of dandruff, psoriasis, or seborrheic dermatitis. Under agency policy, it may not be marketed in OTC drug products for these indications until it has Category I status in an OTC drug monograph or is the subject of an approved application.

Reference

(1) "Acute Eye Irritation Test with 5% Loramine SBU-185," Consultox Laboratories Ltd., London, unpublished study, Comment C0018, Docket Number 82N-0214, Dockets Management Branch.

(2) "Anesthetic Effect on the Eye of SBU-185," Kolmar Research Center, Weisbaden-Igstadt, unpublished study, Comment C0018, Docket Number 82N-0214, Dockets

Management Branch.

(3) "Skin Sensitization Testing of SBU-185," Kolmar Research Center, Weisbaden-Igstadt, unpublished study, Comment C0018, Docket Number 82N-0214, Dockets Management Branch.

(4) "Acute Oral Toxicity Testing in Rats of SBU-185," Kolmar Research Center, Weisbaden-Igstadt, unpublished study, Comment C0018, Docket Number 82N-0214, Dockets Management Branch.

(5) "Sub Acute Dermal Toxicity Testing in Rabbits with SBU-185," Kolmar Research Center, Weisbaden-Igstadt, unpublished study, Comment C0018, Docket Number 82N-0214, Dockets Management Branch.

(6) "Acute Toxicity Test in Mice of SBU-185," Institute for Industrielle und Biologische Forschung, Steinau, unpublished study,

Comment C0018, Docket Number 82N-0214, Dockets Management Branch.

(7) Lubowe, I.I., "The Treatment of Seborrhea Capitis with Undecylenic Alkanolamides," Soap, Perfumery, and Cosmetics, 35:908, 1962.

(8) Alexander, S., "Do Shampoos Affect Dandruff?," The British Journal of Dermatology, 79:92-95, 1967.

(9) "Primary Irritation of Mucus Membranes with 50% SBU-185," Kolmar Research Center, Weisbaden-Igstadt, unpublished study, Comment C0018, Docket Number 82N-0214, Dockets Management

(10) Letter from W.E. Gilbertson, FDA, to Sherex Chemical Company, Inc., April 12, 1984, Comment LET003, Docket Number 82N-0214, Dockets Management Branch.

C. Comments on Labeling

16. Several comments argued that FDA cannot legally and should not, as a matter of policy, prescribe exclusive lists of terms from which indications for use of OTC drug products must be drawn, thus prohibiting alternative OTC labeling terminology that is truthful, not misleading, and intelligible to the consumer. One comment argued that such a policy is an unconstitutional restriction of commercial speech and exceeds FDA's statutory authority. Another comment argued that labeling requirements for OTC drug products can create no inferences for cosmetics, or for the cosmetic aspects of the labeling of those products that are marketed as cosmetics as well as drugs, for example, a cosmetic dandruff shampoo (a product represented both to treat dandruff and to leave the hair clean and manageable). The comment asserted that FDA accepted this principle in the tentative final monograph for OTC skin bleaching drug products, which was published in the Federal Register of September 3, 1982 (47 FR 39115), where it stated that "The agency emphasizes that OTC drug monographs contain appropriate drug labeling claims to be used on OTC drug products and do not preclude the use of acceptable cosmetic claims if the product is both a drug and a cosmetic."

Two comments submitted extensive lists proposing that the following terminology and "other truthful statements" be added as acceptable indications: "fights itching and scalp flaking. . .," "reduces itching, irritation, and skin flaking . . .," "controls itching, redness, and scaling . . .," "helps eliminate . . .," "helps stop . . .,"
"controls recurrence of . .," "reduces recurrence of . . .," "helps prevent . . .," and "fights recurrence of . . ." dandruff, seborrheic dermatitis, and/or psoriasis.

During the course of the OTC drug review, the agency has maintained that the terms that may be used in an OTC

drug product's labeling are limited to those terms included in a final OTC drug monograph. (This policy has become known as the "exclusivity policy.") The agency's position has been that it is necessary to limit the acceptable labeling language to that developed and approved through the OTC drug review process in order to ensure the proper and safe use of OTC drugs. The agency has never contended, however, that any list of terms developed during the course of the review exhausts all the possibilities of terms that appropriately can be used in OTC drug labeling. Suggestions for additional terms or for other labeling changes may be submitted as comments to proposed or tentative final monographs within the specified time periods or through petitions to amend monographs under § 330.10(a)(12). For example, the labeling proposed in this tentative final monograph has been expanded and revised in response to comments received.

During the course of the review, FDA's position on the "exclusivity policy" has been questioned many times in comments and objections filed in response to particular proceedings and in correspondence with the agency. The agency has also been asked by The Proprietary Association to reconsider its position. In a notice published in the Federal Register of July 2, 1982 (47 FR 29002), FDA announced that a hearing would be held to assist the agency in resolving this issue. On September 29. 1982, FDA conducted an open public forum at which interested parties presented their views. The forum was a legislative type administrative hearing under 21 CFR Part 15 that was held in response to a request for a hearing on the tentative final monographs for nighttime sleep-aids and stimulants (published in the Federal Register of June 13, 1978; 43 FR 25544).

After considering the testimony presented at the hearing and the written comments submitted to the record, in the Federal Register of April 22, 1985 (50 FR 15810), FDA proposed to change its exclusivity policy for the labeling of OTC drug products. In the Federal Register of May 1, 1986 (51 FR 16258). the agency published a final rule changing the exclusivity policy and establishing three alternatives for stating the indications for use in OTC drug labeling. Under the final rule, the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a

boxed area designated "APPROVED USES": (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All required OTC drug labeling other than indications for use (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under an OTC drug monograph.

After reviewing the Panel's recommendations as well as the extensive list of indications submitted with the comments, the agency is proposing the following indication for inclusion in the monograph:

(1) ("For relief of" or "Controls") "the symptoms of" (select one or more of the following, as appropriate: "dandruff," "seborrheic dermatitis," and/or "psoriasis.")

(2) The following terms may be used in place of the words "the symptoms of" in the indications in paragraph (1) of this section: ("skin" and/or "scalp," as appropriate) (select one or more of the following: "itching," "irritation," "redness," "flaking," "scaling,") "associated with").

For example, an allowable indication would read as follows: "For the relief of scalp itching and flaking associated with dandruff."

The agency believes that these statements accurately reflect the indications for use of OTC dandruff, seborrheic dermatitis, and psoriasis drug products and provide for the necessary flexibility in developing appropriate indications for the wide range of product formulations. Other terms suggested by the comments are examples of truthful and nonmisleading language that may be used elsewhere in the labeling. In this tentative final monograph, supplemental language relating to indications has been proposed and captioned as Other Allowable Statements. Under FDA's revised exclusivity policy (51 FR 16258). such statements are included at the tentative final stage as examples of other truthful and nonmisleading language that would be allowed elsewhere in the labeling without prior FDA review. In accordance with the revised exclusivity policy, such statements would not be included in a final monograph. However, the agency

has decided that, because these additional terms have been reviewed by FDA, they should be incorporated, wherever possible, in final OTC drug monographs under the heading "Indications" as part of the indications developed under the monograph.

The agency agrees with the comment that the labeling restrictions in this tentative final monograph apply only to products that fall within the statutory definition of "drugs" and not to cosmetic products. This distinction between drugs and cosmetics is discussed in comment 3 above.

The final monograph will cover only the drug use of the active ingredients listed therein. The concentration range, limitations, statements of identity, indications, warnings, and directions established for these ingredients in the monograph will not apply to the use of the same ingredients in products intended solely as cosmetics. However, if a product is intended for both drug and cosmetic use, it must conform to the requirements of the final monograph. In addition to the indications allowed for OTC dandruff, psoriasis, and seborrheic dermatitis drug products, such products may also bear appropriate labeling for cosmetic uses, in conformity with section 602 of the act (21 U.S.C. 362) and the provisions of 21 CFR Part 701. In accordance with the final rule on the agency's "exclusivity policy" (51 FR 16258), it is the agency's view that cosmetic claims may not appear within the boxed area designated "APPROVED USES." As discussed at 51 FR 16264 (paragraph 14), cosmetic claims may appear elsewhere in the labeling but not in the box should manufacturers choose the labeling alternative provided in § 330.1(c)(2) (i) or (iii) for labeling consmetic/drug products.

17. Two comments argued that statements which accurately and effectively identify the product to the nontechnical consumer should be acceptable as a statement of identity. Both comments suggested "antidandruff (product form, such as shampoo)" and "dandruff (product form)" as alternative statements of identity that are truthful, not misleading, and meaningful to laymen.

The agency agrees that the statements of identity suggested by the comments are valid examples of truthful and nonmisleading labeling. The agency concludes that these statements of identity are clearer than those originally recommended by the Panel and has incorporated them in this tentative final monograph as replacements for the statements of identity recommended by the Panel. The agency has also revised

the statements of identity for seborrheic dermatitis, psoriasis, and cradle cap drug products to read as follows: "seborrheic dermatitis (insert product form)," "psoriasis (insert product form)" and "cradle cap (insert product form)".

18. One comment requested that provisions be made to allow any product with more than one applicable indication to combine those indications to eliminate duplicate words because of limited labeling area. The comment noted that the Panel took this approach in § 358.750(a)(6) for the statement of identity declaration. The comment requested that the following new paragraph be added to recommended § 358.750(b): "The statements of indications for any product with more than one indication identified in paragraph (b) of this section may be combined to eliminate duplicate words."

In developing this tentative final monograph, the agency has revised the indications statements in a manner that will avoid duplication. (See comment 16 above.) Because the indications allow sufficient flexibility, the paragraph suggested by the comment is

unnecessary.

19. One comment indicated agreement with the Panel's statement in its discussion of labeling that it is "unacceptable to use any claims related to product performance unless they can be substantiated by adequate scientific data" (47 FR 54655). However, the comment expressed concern that the Panel's comments appear to suggest that the "adequate scientific data" to support the validity of such claims as "fast" or "long acting" should be presented directly to the consumer in product labeling.

While the Panel expressed its convictions that claims related to product performance are "unacceptable" unless supported by scientific data, there was no intention on the part of the Panel to require that such data be routinely forwarded to the

public as part of the labeling.

The OTC drug review program establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. Two principal conditions examined during the review are allowable ingredients and allowable labeling. The FDA has determined that it is not practical-in terms of time, resources, and other considerations—to set standards for all labeling found in drug products. Accordingly, OTC drug monographs regulate only labeling related in a significant way to the safe and effective use of covered products by lay persons. OTC drug monographs establish allowable labeling for the following

items: product statement of identity; names of active ingredients; indications for use; directions for use; warnings against unsafe use, side effects, and adverse reactions; and claims concerning mechanism of drug action.

As with all OTC drug products, dandruff, psoriasis, and seborrheic dermatitis products are expected to achieve their intended results within a reasonable period of time. However, the specific period of time within which these products achieve these results is not related in a significant way to the safe and effective use of the products. Therefore, terms such as "fast" or "long acting" are outside the scope of the OTC drug review.

Such statements or terms will be evaluated by the agency on a productby-product basis, under the provision of section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading. Moreover, any term that is outside the scope of the review, even though it is truthful and not misleading, may not appear in any portion of the labeling required by the monograph and may not detract from such required information. However, terms outside the scope of the monograph may be included elsewhere in the labeling, provided they are not false or

misleading.

20. A number of comments stated that the directions recommended by the Panel in its monograph were too narrow, unnecessarily restrictive, and neither applicable nor adequate for all types of products and dosage forms covered by this monograph. Several comments stated that the Panel had intended to include dosage forms other than shampoos and hairgrooms in the monograph because at 47 FR 54654 the Panel recognized that dandruff, seborrheic dermatitis, and psoriasis preparations were marketed in other forms. The comments urged that these other dosage forms be provided for in the monograph. Two comments specifically urged simpler and more general directions and asked that firms be allowed to include additional directions for use suitable to their specific product form. A number of comments urged that the directions include provisions for preshampoo and postshampoo rinse dandruff formulations as well as bar soap formulations of coal tar.

Other comments objected to the Panel's limitations of "twice-a-week" usage for antidandruff shampoos. The comments stated that if consumers are limited to twice-a-week use of antidandruff shampoos, it is probable that they will use a cosmetic shampoo in between uses of the antidandruff

shampoo because data indicate that people shampoo more frequently than twice a week. Thus, if a consumer used a cosmetic shampoo in conjunction with the twice-a-week usage of a medicated shampoo, especially with one where effectiveness depends on deposition and retention of the active ingredient, the consumer may be removing the active ingredient and, therefore, not achieving the clinically demonstrated benefit. The comments recommended that the directions for antidandruff shampoo products be revised to either "For best results, use regularly," or "For best results, use at least twice a week."

The agency agrees that the directions recommended by the Panel were too narrow and would not be applicable or adequate for all types of products covered by the monograph. Although there are a wide variety of formulations and dosage forms of OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis, all formulations and dosage forms fall into one of three basic groups: products formulated to be applied and then washed off after a brief (a few minutes) exposure (e.g., shampoos, preshampoo rinses, postshampoo rinses); products formulated to be applied up to four times daily and left on the skin or scalp (e.g., creams, ointments, lotions, hairgrooms); and products formulated as soaps, to be used in place of regular soaps, for the treatment of seborrheic dermatitis and psoriasis of the skin. Therefore, to accommodate the various dosage forms of dandruff, seborrheic dermatitis, and psoriasis drug products, the agency is including in the tentative final monograph only brief, required directions for each of the three basic groups of product formulations mentioned above. Manufacturers can then voluntarily expand and supplement these required directions with more detailed instructions applicable to a particular product formulation and dosage form.

The directions proposed in this tentative final monograph are as follows:

- (1) For products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated to be applied and then washed off after brief (a few minutes) exposure (e.g., shampoos, preshampoo rinses, postshampoo rinses). "For best results use at least twice a week or as directed by a doctor."
- (2) For products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated so as to be applied and left on the skin or scalp (e.g., creams,

ointments, lotions, hairgrooms). "Apply to affected areas one to four times daily or as directed by a doctor."

(3) For products containing active ingredients for the control of seborrheic dermatitis or psoriasis of the skin when formulated as soaps. "Use on affected areas in place of your regular soap."

21. Several comments requested that the warning in § 358.750(c)(1)(iii) be deleted from the Panel's recommended monograph. The warning states, "If condition worsens or does not improve after regular use of this product as directed, consult a doctor."

The comments contended that the warning is inappropriate and unwarranted for dandruff control drug products. To support this contention, they cited the Panel's statement that "if dandruff is left untreated, the resulting problems are problems of appearance; no medical disability will result" (47 FR 54652). The comments further argued that this warning is unnecessarily alarming and tends to dilute the value of the other warnings on dandruff control drug products. One of the comments also called attention to the Panel's statement that misdiagnosing seborrheic dermatitis of the scalp as dandruff is not of great consequence because the treatment for both is generally the same, nor is harm likely to follow if the consumer treats psoriasis with an antidandruff product (47 FR 54655). The comment pointed out that the warning in question was intended to apply to conditions that affect the body and do not respond to treatment or that affect a large area of the body.

Another comment argued that this warning should be deleted for psoriasis and seborrheic dermatitis as well as for dandruff control drug products.

The agency agrees that there is no major medical risk in leaving dandruff untreated or in misdiagnosing and treating seborrheic dermatitis or psoriasis as dandruff for a short period. However, the warning in question was intended to ensure that more serious dermatologic conditions that do not respond to treatment with OTC drug products, either because of the severity of the condition or because of misdiagnosis, are treated by a doctor.

The warning also serves to alert individuals who may be particularly sensitive or allergic to the product to discontinue use. Therefore, the warning is being included in the tentative final monograph.

22. Several comments urged deletion of the Panel's recommended warning in § 358.750(c)(1)(iv), "Do not use on children under two years of age except as directed by a doctor," as

unwarranted and unnecessary for dandruff control drug products. One comment cited the Panel's

One comment cited the Panel's statement that because the usual onset of dandruff is in puberty, children under 2 years of age are unlikely to have dandruff (47 FR 54651). Several comments cited the long history of safe marketing and the already adequate margin of safety of dandruff control drug products. Even if the warning were needed for shampoo-type dandruff control drug products, one comment added, it would be unnecessary for medicated hairgroom products because the product vehicle and labeling are directed for use by adolescents and adults.

Another argument was that the warning dilutes the impact of more meaningful warnings and suggests to the consumer that dandruff control drug products are inherently unsafe and would produce unwanted reactions if used on young children. One comment suggested that if the warning is retained it be reworded to read "Use on children under 2 years of age only as directed by a (health professional, or physician or doctor)."

The agency agrees with the comments that the margin of safety of dandruff control drug products is sufficiently great that the occasional exposure of young children to these products should not constitute any major medical problem. In addition, the likelihood of children being exposed to the product is extremely small because children 2 years of age or less are not normally subject to dandruff and consequently do not customarily use these products. The warning against use by children under 2 years of age is therefore unnecessary and it is not being included in the tentative final monograph.

23. One comment subjected to the Panel's recommended warning is § 358.750(c)(1)(ii) "Avoid contact with the eyes, if this happens, rinse thoroughly with water" as unnecessary for antidandruff hair groom ointments intended for application to the scalp. The comment argued that this warning is unnecessary for antidandruff hair groom ointments because the essentially solid form of such products will not run into the eyes and cannot be accidently splashed or poured into the eyes. The comment stated that this request for deletion of the warning is consistent with the agency's position taken in regard to lip balm products at 48 FR 6829. (See the tentative final monograph for OTC skin protectant drug products published in the Federal Register of February 15, 1983; 48 FR 6820.)

The agency agrees that there is less risk of eye contact with the ointment dosage form than with shampoos. However, because the ointment must be applied and rubbed by hand there is the likelihood that the product can be transferred to the eye if the eyes are touched or rubbed or if contact lenses are touched before the hands are cleaned. The warning in question is based primarily on the eye irritation potential of the ingredients in these products, not on the dosage form. While an exception to a similar warning was made for lip balm products, that exception was made in part because lip balms are not only a solid dosage form, but are usually packaged in dispensing containers or holders that avoid all direct contact between the product and the hands. Antidandruff hair groom ointments are not packaged in a similar manner. The agency concludes, therefore, that the warning to avoid eye contact is justified for antidandruff hair groom ointments, and it is being proposed in this tentative final monograph.

24. One comment recommended that the warnings for coal tar products in proposed § 358.750(c)(2)(i) "Use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application" and § 358.750(c)(2)(ii) "Do not use this product in or around the rectum or in the genital area or groin except on the advice of a doctor" be applied only to products formulated for use on the body or for use as a hair groom. The comment argued that the warnings are inappropriate for shampoos which are applied only to the scalp and rinsed off within a few minutes. The comment also mentioned that the Panel had recommended that these warnings apply to "coal tar products for use on the body in the event that such products are included in the monograph" (47 FR 54659).

As the Panel stated in its report (47 FR 54657), coal tar has been shown to produce photosensitivity reactions. Although shampoos remain on the hair and scalp for a short exposure period, residual amounts of the drug will remain on the scalp and hair and could increase the likelihood of a photosensitive reaction. Therefore, the agency agrees with the Panel's recommended warning and it is being proposed in this tentative final monograph.

With respect to the second warning cautioning against use of the product in or around the rectum, genital area, or groin, the agency agrees that the warning is inappropriate for formulations intended to be applied and washed off after brief exposure (e.g.,

shampoos, preshampoo rinses, post shampoo rinses). Therefore, the warning cautioning against use of coal tar products in or around the rectum, genital area, or groin is being proposed in this tentative final monograph only for formulations of coal tar that are intended to be applied and left on the skin.

25. Several comments objected to the recommended warning in § 358.750(c)(3) for selenium sulfide-containing products, "Do not use if you have open sores on your scalp." One comment referred to the statement, "Comparatively little absorption occurs after local application of selenium sulfide to normal skin, but the drug is absorbed more readily from inflamed or damaged epithelium" (Ref. 1), which the Panel used to support the need for such a warning. The comment maintained that this statement is "virtually a truism," in that most drugs are more readily absorbed through damaged skin that intact skin. Therefore, the comment concluded there is no reason why selenium sulfide should be treated differently from any other antidandruff drug in this respect.

One comment stated that the warning is not necessary because the amount of selenium absorbed would not present a health hazard. The comment argued that the low selenium content in OTC dandruff shampoos, together with the short time the product is on the scalp before being rinsed off, would expose the consumer to only a minute fraction of the USDA Recommended Daily Allowance (RDA) for selenium of 50 to 200 mg/day. The comment added that the irritation caused by the contact of detergent in a shampoo with an open sore would discourage repeated application.

A reply comment agreed with the second comment above and also cited an unpublished study in which New Zealand rabbits showed no absorption of selenium above normal dietary levels after application of 2 ml per kg of 1 percent selenium sulfide to abraded and unabraded skin (Ref. 2). Selenium blood levels were measured before application of formulation and 30 minutes and 4 hours after application. The comment argued that millions of ounces of 1 percent selenium sulfide shampoo have been sold OTC since 1971, and that the only incidence of selenium toxicity in humans cited by the Panel was a report by Ransone et al. (Ref. 3) of one patient developing symptoms of selenium toxicity after using a prescription product containing 2.5 percent selenium sulfide in 1961. The comment maintained that there are no actual data to support such a warning and that

conjecture alone, in the absence of factual evidence to the contrary, should not be sufficient to establish the need for an "open sore" warning statement on 1 percent selenium sulfide.

The agency has reviewed the data and arguments submitted by the comments. The agency acknowledges that there appears to be only one case report of selenium toxicity (Ref. 3), which occurred with a prescription product that was 21/2 times more potent than the product covered by this rulemaking. In view of the widespread use of the one percent concentration product with no reports of selenium toxicity, the agency agrees with the comments that the warning in § 358.750(c)(3) cannot be justified for products containing 1 percent selenium sulfide. Therefore, the warning is not being included in this tentative final monograph.

References

(1) Swineyard, E.A., "Surface-Acting Drugs," in "The Pharmacologic Basis of Therapeutics," 5th Ed., edited by L.S. Goodman and A. Gilman, Macmillan Publishing Co., New York, p. 953, 1975

(2) Study #TE78-502, Comment C00022. Docket No. 82N-0214, Dockets Management

Branch.

(3) Ransone, J.W., N.M. Scott, and E.C. Knoblock, "Selenium Sulfide Intoxication," New England Journal of Medicine, 265: 384-385, 1961.

D. Comments on Combinations

26. Several comments noted the Panel's failure to establish a clear combination policy and requested the agency to recognize combinations of two ingredients from different therapeutic categories that are effective for the same condition. Two of the comments cited the General Guidelines for OTC Drug Combination Products dated September 1978 (Ref. 1), as support for their request that these combinations be allowed. The comments specifically asked that the combination of coal tar and salicylic acid for the treatment of psoriasis be recognized as Category I. One comment pointed out that although the mechanism of action for coal tar is not clearly knowm it is obviously different from that of salicylic acid. Thus, these two ingredients would clearly meet the general combination guidelines for ingredients from different therapeutic categories.

A number of comments also urged the agency to recognize combinations of ingredients from different therapeutic categories to treat different concomitant symptoms. The comments faulted the Panel for not allowing combinations of ingredients to treat dandruff, psoriasis, and seborrheic dermatitis with ingredients that provide symptomatic

relief of dryness, itching, and inflammation frequently associated with these conditions. The comments requested that the agency recognize Category I antiprurities, for relief of itching, and Category I skin protectants, for relief of dry flaking skin, as rational combinations with Category I ingredients for the control and treatment of dandruff, seborrheic dermatitis, and psoriasis. The comments specifically requested the agency to recognize as Category I the following combinations: coal tar and salicylic acid; coal tar and hydrocortisone; coal tar and allantoin; coal tar and benzocaine; coal tar and menthol; sulfur and menthol; and coal tar, salicylic acid, and benzocaine.

The agency agrees with the comments that it is rational and consistent with the General Guidelines for OTC Drug Combination Products (Ref. 1) to allow ingredients from different therapeutic categories, to be combined to treat different concomitant symptoms. However, in the case of the combinations mentioned by the comments, the symptoms that would be treated by the various ingredients are not clearly different. For example, although an antipruritic could relieve the itching associated with dandruff, seborrheic dermatitis, or psoriasis, the dandruff/seborrheic dermatitis/ psoriasis ingredients are also capable of relieving the same symptom.

The General Guidelines for OTC Drug Combination Products state that combination OTC drug products must also conform to the requirements of the general OTC drug regulations, specifically 21 CFR 330.10(a)(4)(iv), which require that each active ingredient in a combination make a contribution to the claimed effect. In the combinations mentioned by the comments, because the ingredients are capable of relieving the same symptoms. the contribution would need to be a demonstration that combination is somehow better than the individual ingredients used alone, e.g., the symptoms are relieved sooner, or the combination provides greater relief in reducing the severity of the symptoms.

The Panel did not find the data submitted to it to be adequate to establish general recognition of the effectiveness of such combinations, and the comments did not submit any additional data. Because the contribution of the ingredients in the combinations mentioned by the comments has not been adequately demonstrated, the agency is not including these combinations in the tentative final monograph.

References

- (1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D-0322, Dockets Management
- 27. One comment objected to the Panel's conclusion that ". . . any combination product containing a Category II ingredient is Category II." The comment contended that agents listed as Category II single ingredients may possibly be more effective in combination and that the action of each agent may complement the other so that the resulting combination is safe and effective. The comment specifically asked for reconsideration of a combination of phenol and sodium chloride for psoriasis of the scalp so that this combination is not forced off the market.

The agency agrees with the comments that there may be circumstances in which an ingredient may not be appropriate for use as a single ingredient but may be appropriate in a combination product. Paragraph 5 of the agency's General Guidelines for OTC Drug Combination Products (Ref. 1) states: "In some cases an ingredient may be appropriate for use only in a specific combination or data may be available only to support the use of the ingredient in combinations but not as a single ingredient. In such cases the ingredient will be placed in Category I only in permissible combinations and not as a single ingredient."

With respect to the comment's request that the agency reconsider the classification of phenol and sodium chloride for psoriasis of the scalp, the agency notes that the data submitted to the Panel did not show any contribution of the sodium chloride to the combination of phenol and sodium chloride, nor were any additional data submitted with the comment. Should such data become available, the agency would consider classification of such a combination.

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products, September 1978," Docket No. 78D-0322, Dockets Management

II. The Agency's Tentative Adoption of the Panel's Report

- A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions
- 1. Summary of Ingredient Categories

The agency has reviewed all claimed active ingredients submitted to the

Panel, as well as other data and information available at this time, and has made some changes in the categorization of dandruff, seborrheic dermatitis, and psoriasis active ingredients recommended by the Panel. As a convenience to the reader, the following list is included as a summary of the categorization of dandruff, seborrheic dermatitis, and psoriasis active ingredients and uses recommended by the Panel and the proposed categorization by the agency.

CATEGORIZATION OF INGREDIENTS

Incompliant.	Pane	el	Agency				
Ingredient	Category	Uses ¹	Category	Uses			
Alleyl	111	D	111	D			
isoquinolin-	All			-			
ium bromide.			-93				
Allantion	111	D. S. P.	181	D, S, P			
Benzalkonium	101	D	101	D			
chloride.							
Benzethonium	111 :	D, C	111	D, C			
chloride.				22 1			
Benzocaine	11	P		P			
Borate	II	D, S	И	D, S			
preparations.		4					
Captan	111,	D					
Chloroxylenol	#1		HI				
Coal tar	1, 111 2	D, S, P	ł	D, S, P			
preparations.	100	2	100				
Celloidal	11	D	· II	D			
oatmeal.		-	-	P			
Cresol	11	P		1070			
Ethohexadiol	Ш						
Eucalyptol		D					
Hydrocortisone	111	D, S, P.	13	S, P			
preparations.		000		000			
Juniper tar	III						
Lauryl	181	D	- 111	D			
isoquinolin-	1000			1 11			
ium bromide.	-111	D, S, P.		D, S, F			
Menthol	Control of the second			P			
Mercury oleate.	HI	P		C			
Methylben- zethonium	19t	· · · · · · · · · · · · · · · · · · ·	1111	0			
chloride.		100	1/1 4/2 1				
Methyl		D	111	D			
salicylate.	311	No.	411,-1111111111111111111111111111111111	100			
Phenol and	101	S. P	. 101	S, P			
phenolate	111			-			
sodium.	The state of the s	1	3 19	1			
Pine tar	111	D. S. P.		D, S, 1			
preparations.		3 30000000	-	20000			
Providone-	101	. D. S	10	D, S			
iodine.	1 1 1 1 1 1	1 10 30	11000	1 12			
Pyrithione zinc.	. 1	. D, S		D. S			
Resorcinol	. 11	. P	. H	P			
Salicylic acid	1	D, S, P.		D. S.			
Selenium	11	. D		D, S			
sulfide.				1			
Sodium	H	D, S		D, S			
salicylate.	1	10.	4	1			
Sulfur							
Thymol				A DESCRIPTION OF THE PERSON OF			
Undecylenate	111	D, S, P.		. D, S,			
preparations.	1	1	The state of the s				

C=Cradle cap, D=Dandruff, S=Seborrheic dermatitis,

1 C=Cradle cap, D=Dandruff, S=Seborrheic dermatilis, P=Psonaisis
2 The Panel classified coal tar in Category I for use in a shampoo only and in Category III for other uses.
3 Indications for hydrocorusone preparations for seborrheic dermatitis and psonaisis are being included in the rulemaking for OTC external analgesic drug products (See proposed rule published elsewhere in this issue of the Federal Register). Hydrocortisone preparations remain in Category III for the treatment of dandruff.
4 This tentative final monograph contains labeling for "cradle cap" even though no ingredients are included in Category I for this use at this time. In the event that new data submitted to the agency during the allotted 12-month comment and new data period are not sufficient to establish "monograph conditions" for this use, it will not be included in the final monograph.

2. Testing of Category II and Category III Conditions

Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any dandruff, seborrheic dermatitis, and psoriasis ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the Federal Register of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel's report and recommended monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency

- 1. Because of the number of changes that have been made, as summarized below, many of the section and paragraph numbers have been redesignated in this tentative final monograph.
- 2. The agency has classified coal tar in Category I for use in dandruff, seborrheic dermatitis, and psoriasis and added the following warnings: (1) "Do not use for prolonged periods without consulting a doctor." (2) "Do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescripion drugs unless directed to do so by a doctor." (See comment 5.)
- 3. The agency has proposed standards for coal tar preparations in this tentative final monograph. (See comment 7.)
- 4. The agency has changed the terms in the definitions section of the monograph and added additional information to better describe the conditions under consideration.
- 5. A seborrheic dermatitis indication has been proposed for selenium sulfide in the tentative final monograph. (See comment 8.)
- 6. The lower limit of the concentration range of pyrithione zinc in formulations intended to be applied and washed off after a brief exposure has been revised from 1 percent to 0.95 percent. The monograph also proposes that the concentration range for formulations

intended to remain on the scalp is 0.1 to 0.25 percent. (See comments 10 and 11.)

7. An indication for hydrocortisone for the symptomatic relief of seborrheic dermatitis and psoriasis is being proposed elsewhere in this issue of the Federal Register for inclusion in the rulemaking for OTC external analgesic drug products (21 CFR Part 348). Hydrocortisone is not being included in the rulemaking for OTC dandruff, seborrheic dermatitis, and psoriasis drug products to avoid duplication and overlap between rulemakings. (See comment 13.)

8. The agency has modified the indications statements to provide for greater flexibility in developing indications for the wide range of product formulations. Other allowable statements have been included in this tentative final monograph under the heading Other Allowable Statements.

(See comment 16.)

9. The statement of identity for dandruff preparations has been changed to read "dandruff (insert product form)" or "antidandruff (insert product form)". The statements of identity for seborrheic dermatitis, psoriasis, and cradle cap products have been similarly revised. (See comment 17.)

10. The agency has clarified the directions for use in this tentative final monograph to accommodate the various dosage forms of dandruff, seborrheic dermatitis, and psoriasis drug products.

(See comment 20.)

11. The agency has not included the warning "Do not use on children under two years of age except as directed by a doctor" in this tentative final monograph. (See comment 22.)

12. The agency has not included the warning "Do not use if you have open sores on your scalp" for selenium sulfide in this tentative final monograph. (See

comment 25.)

13. In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and any applicable OTC drug regulations will give manufacturers the option of using either the word "physician" or the word "doctor." This tentative final monograph proposes that option.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the

Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC dandruff, seborrheic dermatitis, and psoriasis drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Public Law 95-354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC dandruff, seborrheic dermatitis, and psoriasis drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC dandruff, seborrheic dermatitis, and psoriasis drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by November 28, 1986. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined that under 21 CFR 25.24(c)(6) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is

required.

Interested persons may, on or before September 29, 1986, submit to the Dockets Management Branch (HFA– 305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and

time requested. Written comments on the agency's economic impact determination may be submitted on or before November 28, 1986. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

Interested persons, on or before July 30, 1987, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before September 30, 1987. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA-305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on September 30, 1987. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the Federal Register, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 358

OTC drugs; Corn and callus remover drug products; Dandruff, seborrheic dermatitis, and psoriasis drug products; Ingrown toenail relief drug products, Nailbiting and thumbsucking deterrent drug products; Pediculicide drug products; Skin bleaching drug products; and Wart remover drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended by adding a new Part 358 consisting at this time of Subpart H, to read as follows:

PART 358-MISCELLANEOUS **EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE**

Subpart H-Drug Products for the Control of Dandruff, Seborrhelc Dermatitis, and

358.701 Scope.

358.703 Definitions.

358.710 Active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis.

358.712 Active ingredients for the control of cradle cap. [Reserved]

358.720 Permitted combinations of active ingredients.

358.750 Labeling of drug products for the control of dandruff, seborrheic dermatitis, or psoriasis.

358.752 Labeling of drug products for the control of cradle cap.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

Subpart H-Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis

§ 358.701 Scope.

- (a) An over-the-counter dandruff, seborrheic dermatitis, or psoriasis drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1.
- (b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 358.703 Definitions.

As used in this subpart:

- (a) Coal tar. The tar used for medical purposes that is obtained as a byproduct during the destructive distillation of bituminous coal at temperatures in the range of 900° C to 1100° C. It may be further processed using either extraction with alcohol and suitable dispersing agents and maceration times or fractional distillation with or without the use of suitable organic solvents. The concentration of the coal tar portion of the final product should be in a relative concentration range of 0.5 to 5 percent
- (b) Cradle cap. Infantile seborrheic dermatitis.

(c) Dandruff. A condition involving an increase rate of shedding of dead epidermal cells of the scalp.

(d) Psoriasis. A condition of the scalp or body characterized by irritation, itching, redness, and extreme excess shedding of dead epidermal cells.

(e) Seborrheic dermatitis. A condition of the scalp or body characterized by irritation, itching, redness, and excess shedding of dead epidermal cells.

§ 358.710 Active ingredients for the control or dandruff, seborrheic dermatitis, or psoriasis.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient:

(a) Active ingredients for the control of dandruff.

(1) Coal tar, 0.5 to 5 percent. (2) Pyrithione zinc, 0.95 to 2 percent when formulated to be applied and then

washed off after brief exposure. (3) Pyrithione zinc, 0.1 to 0.25 percent when formulated to be applied and left

on the skin or scalp. (4) Salicylic acid, 1.8 to 3 percent.

(5) Selenium sulfide, 1 percent.

(6) Sulfur, 2 to 5 percent.

(b) Active ingredients for the control of seborrheic dermatitis.

(1) Coal tar, 0.5 to 5 percent.

(2) Pyrithione zinc, 0.95 to 2 percent when formulated to be applied and then washed off after brief exposure.

(3) Pyrithione zinc, 0.1 to 0.25 percent when formulated to be applied and left on the skin or scalp.

(4) Salicylic acid, 1.8 to 3 percent.

(5) Selenium sulfide, 1 percent.

(c) Active ingredients for the control of psoriasis.

(1) Coal tar, 0.5 to 5 percent.

(2) Salicylic acid, 1.8 to 3 percent.

§ 358.712 Active ingredients for the control of cradle cap. [Reserved]

§ 358.720 Permitted combinations of active ingredients.

Salicylic acid identified in § 358.710(a)(4) may be combined with sulfur identified in § 358.710(a)(6) provided each ingredient is present within the established concentration and the product is labeled for the control of dandruff.

§ 358.750 Labeling of drug products for the control of dandruff, seborrheld dermatitis, or psoriasis.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product with one or more of the following as appropriate:

(1) "Dandruff (insert product form)" or "antidandruff (insert product form)".

(2) "Seborrheic dermatitis (insert product form)".

(3) "Psoriasis (insert product form)".

(b) Indications. The labeling of the product states, under the heading 'Indications," any of the phrases listed in this paragraph. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed below, may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) ("For relief of" or "Controls") "the symptoms of' (select one or more of the following, as appropriate: "dandruff," "seborrheic dermatitis," and/or

"psoriasis."

(2) The following terms may be used in place of the words "the symptoms of" in the indications in paragraph (1) of this section: ("skin" and/or "scalp," as appropriate) (select one or more of the following: "itching," "irritation," "redness," "flaking," "scaling,") "associated with").

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) For products containing any ingredient identified in § 358.710. (i) "For external use only.

(ii) "Avoid contact with the eyes-if this happens, rinse thoroughly with water.

(iii) "If condition worsens or does not improve after regular use of this product as directed, consult a doctor.'

(2) For any product containing coal tar identified in § 358.710(a), (b), or (c). (i) "Use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application."

(ii) "Do not use for prolonged periods

without consulting a doctor.

(3) For products containing coal tar when formulated to be applied and left on the skin (e.g., creams, ointments, lotions). "Do not use this product in or around the rectum or in the genital area or groin except on the advice of a doctor.'

(4) For products containing coal tar identified in § 358.710(c) for the control of psoriasis. "Do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to do so by a doctor.'

(5) For products containing any ingredient identified in § 358.710(b) or (c) for the control of seborrheic dermatitis or psoriasis. "If condition covers a large area of the body, consult your doctor before using this product."

(d) Directions. The labeling of the product contains the following information under the heading "Directions". More detailed directions applicable to a particular product formulation may also be included.

(1) For products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated to be applied and then washed off after brief (a few minutes) exposure (e.g., shampoos, preshampoo rinses, postshampoo rinses). "For best results use at least twice a week or as directed by a doctor."

(2) For products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated so as to be applied and left on the skin or scalp (e.g., creams, ointments, lotions, hairgrooms). "Apply to affected areas one to four times daily or as directed by a doctor."

(3) For products containing active ingredients for the control of seborrheic dermatitis or psoriasis of the skin when formulated as soaps. "Use on affected areas in place of your regualr soap."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

(f) Other allowable statements. The following phrases are considered truthful and nonmisleading and may be used elsewhere in the labeling in place of the term "For the relief of" or "Controls" in the indication statements identified in paragraph (b) of this section: "fights," "reduces," "helps eliminate," "helps stop," "controls recurrence of," "fights recurrence of," "helps prevent recurrence of," "reduces recurrence of," "helps eliminate recurrence of," "helps stop recurrence of," "helps stop recurrence of," "helps stop recurrence of,"

§ 358.752 Labeling of drug products for the control of cradle cap.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as "cradle cap (insert product form)."

(b) Indications. The labeling of the product states, under the heading "Indications," the following: "Relieves scaly inflammation of the scalp associated with cradle cap." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed above, may also be used, as provided in § 330.1(c)(2), subject to the provisions in section 502 of the act relating to

misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only."

(2) "Avoid contact with the eyes—if this happens, rinse thoroughly with water."

(3) "If condition worsens or does not improve after regular use of this product as directed, consult a doctor."

(d) Directions. [Reserved]

(e) The word "physician" may be substituted for the wold "doctor" in any of the labeling statements in this section.

Dated: May 3, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86–17040 Filed 7–29–88; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 348

[Docket No. 78N-0301]

External Analgesic Drug Products for Over-the-Counter Human Use; Amendment to Tentative Final Monograph

ACTION: Further notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of an amended tentative final monograph that modifies the indications for which overthe-counter (OTC) hydrocortisonecontaining external analgesic drug products are generally recognized as safe and effective and not misbranded, by adding an indication for use in the symptomatic treatment of seborrheic dermatitis and psoriasis. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products and public comments on the advance notice of proposed rulemaking for OTC dandruff, seborrheic dermatitis, and psoriasis drug products that was based on those recommendations. The agency's proposal concerning OTC dandruff, seborrheic dermatitis, and psoriasis drug products is being published elsewhere in this issue of the Federal Register. These proposals are part of the ongoing review

of OTC drug products conducted by FDA.

DATES: Written comments objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by September 29, 1986. New data by July 30, 1987. Comments on the new data by September 30, 1987. These dates are consistent with the time periods specified in the agency's revised procedural regulations for reviewing and classifying OTC drugs (21 CFR 330.10). Written comments on the agency's economic impact determination by November 28, 1986.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 4, 1979 [44 FR 69768), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC external analgesic drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these drug classes. Interested persons were invited to submit comments by March 6, 1980. Reply comments in reponse to comments filed in the initial comment period could be submitted by April 3, 1980.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC external analgesic drug products was published in the Federal Register of February 8, 1983 (48 FR 5852.)

In the Federal Register of December 3, 1982 (47 FR 54646), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these

drug classes. Interested persons were invited to submit comments by March 3, 1983. Reply comments in response to comments filed in the initial comment period could be submitted by April 4, 1983.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA—305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

In this tentative final monograph (proposed rule) to amend Part 348 (as proposed in the Federal Register of February 8, 1983; 48 FR 5852), FDA states for the first time its position on the use of OTC hydrocortisone-containing external analgesic drug products for the relief of symptoms associated with seborrheic dermatitis and psoriasis. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC external analgesic drug products.

This proposal constitutes FDA's tentative adoption of the Miscellaneous External Panel's conclusions and recommendations on OTC drug products containing hydrocortisone and hydrocortisone acetate for the symptomatic relief of seborrheic dermatitis and psoriasis as modifed on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above).

The OTC procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II,

and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

A. The Agency's Tentative Adoption of the Panel's Report

1. Summary of the agency's changes in the Panel's recommendations. The agency has reviewed the Miscellaneous External Panel's recommendations regarding the use of OTC drug products containing 0.25 to 1 percent hydrocortisone for the relief of symptoms associated with seborrheic dermatitis and psoriasis. As discussed in comment 13 of the tentative final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products (published elsewhere in this issue of the Federal Register), the agency has tentatively concluded that data support the general recognition of the safety and effectiveness of using hydrocortisone and hydrocortisone acetate in providing temporary symptomatic relief of the symptoms associated with seborrheic dermatitis and psoriasis. The agency also noted that 0.25 to 0.5 percent concentrations of hydrocortisone and hydrocortisone

acetate were determined to be generally recognized as safe and effective ingredients for OTC use in relieving the symptoms associated with a variety of dermatoses as part of the tentative final monograph for OTC external analgesic drug products. The agency further stated that it would be more appropriate to amend the tentative final monograph for OTC external analgesic drug products to add seborrheic dermatitis and psoriasis to the list of conditions for which hydrocortisone has been found to be safe and effective in providing symptomatic relief rather than to include hydrocortisone as an ingredient in the tentative final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products. Therefore, the agency is amending the tentative final monograph for OTC external analgesic drug products to revise the indications for use for hydrocortisone and hydrocortisone acetate to include seborrheic dermatitis and psoriasis to the list of conditions for which these ingredients have been found to be safe and effective in providing symptomatic relief. The agency is not amending the external analgesic tentative final monograph to include concentrations greater than 0.5 to 1 percent at this time. At a later date, the agency will consider the request that concentrations of hydrocortisone greater than 0.5 up to 1 percent be included in the final rule for OTC external analgesic drug products. Hydrocortisone preparations remain in Category III for the treatment of dandruff.

2. Testing of Category II and Category III conditions. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any external analgesic ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the Federal Register of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts

of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC external analgesic drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Public Law 96-354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC external analgesic drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC external analgesic drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC external analgesic drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on external analgesic drug products for use in the treatment of seborrheic dermatitis and psoriasis, a period of 120 days from the date of publication of this proposed rulemaking in the Federal Register will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency previously invited public comment in the advance notice of proposed rulemaking for OTC dandruff, seborrheic dermatitis and psoriasis drug products regarding any impact that that rulemaking would have on OTC dandruff, seborrheic dermatitis, and psoriasis drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by

November 28, 1986. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined that under 21 CFR 25.24(c)(6) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Exclusivity of Labeling

In the Federal Register of April 22, 1985 (50 FR 15810) the agency proposed to change its "exclusivity" policy for the labeling of OTC drug products that has existed during the course of the OTC drug review. Under that policy, the agency had maintained that the terms used in an OTC drug product's labeling were limited to those terms included in a final OTC drug monograph.

In the Federal Register of May 1, 1986 (51 FR 16258), the agency published a final rule changing the exclusivity policy and establishing three alternatives for stating the indications for use in OTC drug labeling. Under the final rule, the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All required OTC drug labeling other than indications for use (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under an OTC drug monograph. The proposed rule in this document is subject to the final rule revising the exclusivity policy

Interested persons may, on or before September 29, 1986, submit to the Dockets Management Branch (HFA– 305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before November 28, 1986. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

Interested persons, on or before July 30, 1987, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before September 30, 1987. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Docket Management Branch (HFA-305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on September 30, 1987. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the Federal Register, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 348

OTC drugs, External analgesic drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 348 as proposed in the Federal Register of February 8, 1983; 48 FR 5852, as follows:

PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for Part 348 would be revised to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

2. In Subpart C, § 348.50(b) introductory text, (b)(3) introductory text, (3) (i) and (ii) would be revised to read as follows:

§ 348.50 Labeling of external analgesic drug products.

(b) Indications. The labeling of the product states, under the heading "Indication(s)," any of the phrases listed in this paragraph, as appropriate. Other

truthful and nonmisleading statements, describing only the indications for use that have been established and listed below, may also be used, as provided in § 330.1(c)(2), subject to the provisions in section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(3) For products containing any external analgesic active ingredients indentified in § 348.10(d). The labeling of the product contains one of the following indications: (i) "For the temporary relief of itching associated with minor skin irritations and rashes" [which may be followed by: "due to" (select one or more of the following: "eczema," "insect bites," "poison ivy,

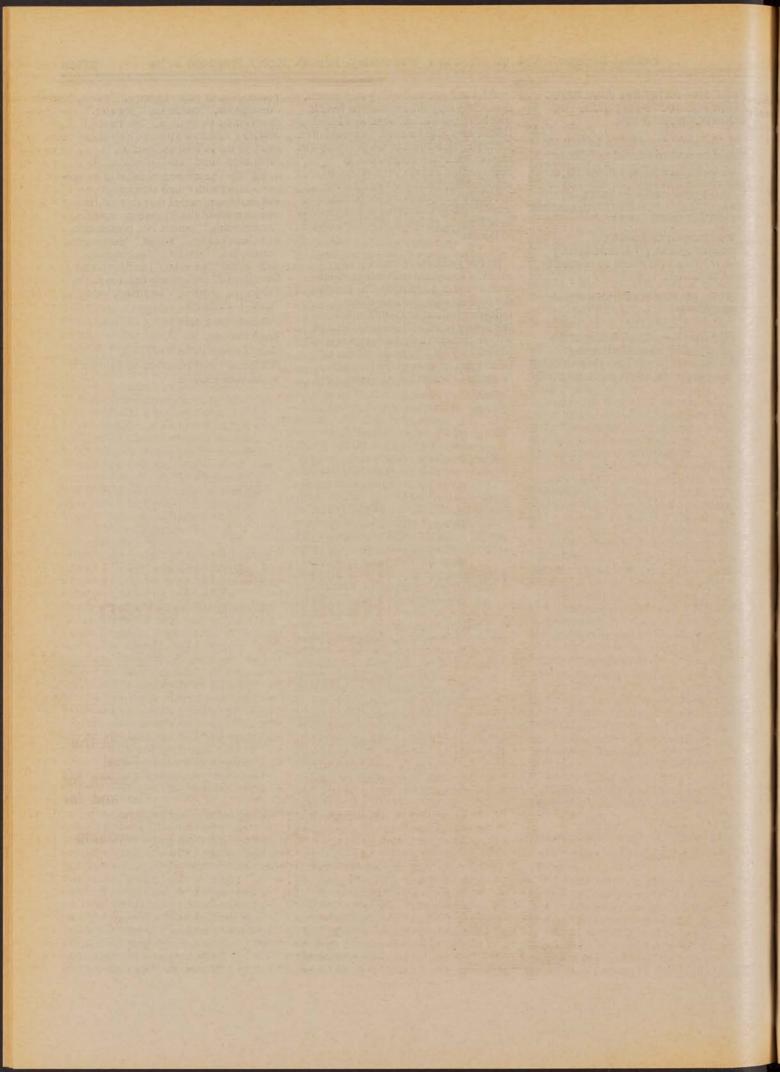
poison oak, or poison sumac," "soaps,"
"detergents," "cosmetic," "jewelry,"
"seborrheic dermatitis," "psoriasis")
and/or ("and for external" (select one or
more of the following: "genital,"
"feminine," and "anal") "itching")].

(ii) "For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to" (select one or more of the following: "eczema," "insect bites," "poison ivy, poison oak, or poison sumac," "soaps," "detergents," "cosmetics," "jewelry," "seborrheic dermatitis," "psoriasis") and/or ("and for external" (select one or more of the following: "genital," "feminine," and "anal") "itching").

Dated: May 3, 1986.

Frank E. Young,

Commissioner of Food and Drugs.
[FR Doc. 86–17037 Filed 7–29–86: 8:45 am]
BILLING CODE 4160–01-M





Wednesday July 30, 1986

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 344

Topical Otic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph To Include Drug Products for the Prevention of Swimmer's Ear and for the Drying of Water-Clogged Ears; Further Notice of Proposed Rulemaking



DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 344

[Docket No. 77N-334S]

Topical Otic Drug Products for Overthe-Counter Human Use; Tentative Final Monograph To Include Drug Products for the Prevention of Swimmer's Ear and for the Drying of Water-Clogged Ears

AGENCY: Food and Drug Administration.
ACTION: Further notice of proposed
rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that amends the tentative final monograph for over-thecounter (OTC) topical otic drug products by including conditions under which OTC topical otic drug products are generally recognized as safe and effective and not misbranded for the prevention of "swimmer's ear" and for the drying of "water-clogged" ears. "Swimmer's ear" is the common name for external otitis, a bacterial or fungal infection of the external ear canal that may occur following the retention of water in the ear; "water-clogged" ears refers to the retention of water in the ears after swimming, showering, or bathing. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. FDA issued a notice of proposed rulemaking on OTC topical otic drug products in the Federal Register of July 9, 1982 (47 FR 30012). However, the tentative final monograph only included topical otic drug products used as earwax removal aids. Topical otic drug products used for the prevention of swimmer's ear and the drying of water-clogged ears are addressed in this tentative final monograph. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by September 29, 1986. New data by July 30, 1987. Comments on the new data by September 30, 1987. These dates are consistent with the time periods specified in the agency's revised procedural regulations for reviewing and

classifying OTC drugs (21 CFR 330.10). Written comments on the agency's economic impact determination by November 28, 1986.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 16, 1977 (42 FR 63556), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical otic drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn. and Sunburn Prevention and Treatment Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in topical otic drug products. Interested persons were invited to submit comments by March 16, 1978. Reply comments in response to comments filed in the initial comment period could be submitted by April 14, 1978.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

In the December 16, 1977 advance notice of proposed rulemaking on OTC topical otic drug products, the Panel discussed the treatment of swimmer's ear (42 FR 63565), but did not address the prevention of swimmer's ear or the drying of water-clogged ears.

In response to the advance notice of proposed rulemaking, two comments were received concerning both the prevention and the treatment of swimmer's ear. The agency responded to the comments in the notice of proposed rulemaking on OTC topical otic drug products, published in the Federal Register of July 9, 1982 (47 FR 30017). The agency stated that, because no clinical data had been submitted, there was no basis for including the prevention of swimmer's ear as an indication for OTC topical otic drug products.

In response to that notice of proposed rulemaking, comments were submitted by one health professional regarding the prevention of swimmer's ear and by one drug manufacturer regarding the prevention of swimmer's ear and the drying of water-clogged ears. Copies of the comments received are on public display in the Dockets Management Branch.

Because active ingredients and claims for the prevention of swimmer's ear and the drying of water-clogged ears were not included in the Panel's report, or substantively addressed by the agency in the tentative final monograph on OTC topical otic drug products, this tentative final monograph is being published to obtain public comment on such ingredients and claims.

The advance notice of proposed rulemaking, which was published in the Federal Register of December 16, 1977 (42 FR 63556), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the notice of proposed rulemaking, which was published in the Federal Register of July 9, 1982 (47 FR 30012), was designated as a "tentative final monograph." The present documentis also designated as a "tentative final monograph." The legal status of the tentative final monographs, however, is that of a proposed rule. In this tentative final monograph (proposed rule), FDA states for the first time its position on the establishment of a monograph for OTC topical otic drug products for the prevention of swimmer's ear and the drying of waterclogged ears. Final agency action on this matter will occur with the publication at a future date of a final rule for OTC topical otic drug products.

This proposed rule amends Part 344 (as set forth in the tentative final monograph on OTC topical otic drug products (earwax removal aids) that was published in the Federal Register of July 9, 1982 (47 FR 30012)) in Subpart A by adding in § 344.3, new paragrpahs (c), (d), (e), and (f); in Subpart B by revising the heading of § 344.10 and adding new §§ 344.12 and 344.14; and in Subpart C by revising the heading of § 344.50 and adding new §§ 344.52 and 344.54.

This proposal constitutes FDA's tentative conclusions on OTC topical otic drug products for the prevention of swimmer's ear and the drying of water-clogged ears. The agency emphasizes that no topical otic drug products for these conditions have been determined to be generally recognized as safe and effective and not misbranded. However, the agency is proposing Category I labeling in this document in the event that data are submitted that result in the

upgrading of any ingredient(s) to monograph status in the final rule.

The OTC procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

In the previous tentative final monograph (47 FR 30012), the agency advised that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the event that new data submitted to the agency during the allotted 12-month comment and new data period are not sufficient to establish "monograph conditions" for OTC topical otic drug products for the prevention of swimmer's ear and the drying of water-clogged ears, and final rule will declare these products to be new drugs under

section 201(p) of the Federal Food, Drug, and Cosmetic Act, for which new drug applications approved under section 505 of the act and 21 CFR Part 314 are required for marketing. Such rule will also declare that in the absence of an approved new drug application, these products would be misbranded under section 502 of the act. The rule will then be incorporated into 21 CFR Part 310, Subpart E—Requirements for Specific New Drugs or Devices, instead of into an OTC drug monograph in Part 344.

I. The Agency's Tentative Conclusions on the Comments

1. One comment stated that swimmer's ear is one of the most common infections that occurs during the swimming season and requested that a solution of 2 percent acetic acid in distilled water for the prevention of external otitis (swimmer's ear) be included in the monograph for OTC topical otic drug products. The comment also stated that the use of 2 percent acetic acid in the external ear canal would maintain a safe acid pH, which is important in order to avoid swimmer's ear. In support of its request, the comment submitted a study in which 2 percent acetic acid in water was used to prevent swimmer's ear in 25 patients

As discussed in the Panel's report (42 FR 63565), external otitis, an infection of the skin lining the external auditory canal, is one of the most common diseases of the ear. One type of external otitis is called "diffuse external otitis" and is commonly known as "swimmer's ear." It occurs with greater frequency during hot, humid weather and has been reported to occur in divers and swimmers. Such factors as high environmental humidity, high temperature, prolonged exposure of the ears to moisture, and local trauma to the ear canal are recognized as important in the development of swimmer's ear.

The external auditory canal is a culde-sac, well suited for the collection of moisture, that provides a basis for infection. Disruption of the skin lining the external auditory canal and the action of accumulated moisture, or the use of instruments to clear the ear canal of water after bathing, showering, or swimming may cause maceration, fissuring, or laceration of the skin lining and provide a favorable environment for the growth of bacteria. The invading organism commonly found in external otitis is Pseudomonas aeruginosa (P. aeruginosa), a gram-negative bacillus (Refs. 2 and 3). However, Escherichia coli, Proteus vulgaris, Staphylococcus aureus (Ref. 2), or, rarely, a fungus (Refs. 2 and 3), may be found. Certain persons

(e.g., allergic individuals) are more prone then others to develop swimmer's ear (Ref. 2). Boies (Ref. 4) notes that infections may also occur as a result of a change of the canal skin from a normal acid pH to an alkaline pH. Prolonged exposure to moisture tends to raise the normal skin pH, improving the growth medium for bacteria (Ref. 5).

Symptoms of swimmer's ear are related to the severity of the pathologic conditions. Persons with swimmer's ear complain of itching and pain. There may be a "foul-smelling discharge, and loss of hearing if the canal becomes swollen or filled with purulent (pus-containing) debris. The skin of the external auditory canal appears red, swollen, and littered with moist, purulent debris" (Ref. 2).

In its published report, the Panel discussed the treatment but not the prevention of swimmer's ear. (The Panel believed, and the agency concurs, that the "treatment" of swimmer's ear is a Category II condition because such conditions require the diagnosis and continuous supervision of a physician (47 FR 30017).) However, the Panel did review acetic acid (2 to 5 percent) and was prepared to place this ingredient in Category I for use as "an aid in restoring the normal acid mantle of the ear canal skin-as a prophylaxis or aid in preventing swimmer's ear" (Ref. 6). The Panel later decided, however, that it would not discuss acetic acid for the prevention of swimmer's ear in its report because the ingredient had not been submitted for review (Ref. 7).

The agency recognizes that there is a population that is prone to develop swimmer's ear and that the availability of an OTC drug product to prevent the occurrence of this condition would benefit the consumer. Acetic acid and other ingredients, such as alcohols, are frequently mentioned in the literature as aids in the prevention of swimmer's ear. A number of marketed OTC drug products are promoted for the prevention of swimmer's ear, but their effectiveness, and in some cases, safety, has not been proven. The agency believes that the prevention of swimmer's ear is a Category I claim; however, adequate data must be submitted to demonstrate the safety and effectiveness of any ingredient(s) making such a claim.

The agency has considered data on 2 percent acetic acid for the prevention of swimmer's ear and concludes that the data are inadequate to support this claim for this ingredient. The data reviewed by the agency consist of the Panel's interim working papers (Ref. 6) and summary minutes (Ref. 7), published references on acetic acid (Refs. 8

through 14), and data submitted by the

comment (Ref. 1).

During its deliberations the Panel reviewed data on the safety and effectiveness of acetic acid (Refs. 6 through 13). The Panel concluded that 2 to 5 percent acetic acid is safe and effective for topical use in the ear canal to restore the acid mantle of the skin. which is normally pH 6 to 6.5, and as a bactericidal drug effective against the common pathogens found in external otitis (Ref. 6). The Panel made the following comments: Acetic acid is available in three concentrations: glacial acetic acid U.S.P. (99 percent), acetic acid U.S.P. (36 percent), and diluted acetic acid (household vinegar) (5 percent) (Refs. 6 and 8). Acetic acid is completely innocuous to the tissues; it is a part of body metabolism and there is no sensitization (Ref. 6). The use of vinegar (5 percent acetic acid) in medicine dates back to antiquity; most likely, "vinegar was the first antibiotic known to man." During World War I, wound infections were treated effectively with wet dressings of 1 percent acetic acid, and this solution was effective in inhibiting the growth of P. aeruginosa (Ref. 9).

Acetic acid is effective as a bactericidal agent against a wide range of micro-organisms, both gram-negative and gram-positive pathogens. Cultures of the bacteria found in the external ear canal in acute infectious external otitis cases were studied by Jones et al. (Ref. 10). In the cultures with acetic acid added (at concentrations of 1, 2, 3, 4, and 5 percent) there was no growth. When other acid solutions with the same pH as solutions of 5 and 25 percent acetic acid (i.e., hydrochloric acid, citric acid, and lactic acid) and when sodium acetate were used, there was heavy growth on all plates. Solutions of acetic acid weaker than 1 percent are not consistently bactericidal in vitro.

The bactericidal and therapeutic effect of 2 percent acetic acid has also been demonstrated in vivo. Ochs (Ref. 11) reported on a series of 142 successive ear cases in which 2 percent acetic acid in propylene glycol was used to treat external otitis without a single failure. Ochs (Ref. 9) also reported treating 38 patients with chronic middle-ear infections using household vinegar. In 30 of the patients, he reported that the infection was quickly and effectively eliminated.

Goffin (Ref. 11) reported on two groups of patients with external otitis. One group, with an ear canal pH over 6.3, received 2 percent acetic acid in propylene glycol. The second group complained mostly of itching and had an ear canal pH under 6.3. This group was

treated with a formulation containing acetic acid in propylene glycol with hydrocortisone added. All canals cleared within 7 days in the first group and within 10 days in the second group. The author attributed the difference in the number of days required to clear the ear canals to the pH and stated that cases with a pH higher than 6.3 appeared to be primarily infectious and responded promptly to antibacterial therapy. However, in cases with a pH lower than 6.3, factors other than infection, such as neurodermatitis. seborrheic dermatitis, and eczema, were more significant; and these cases responded less promptly even when hydrocortisone was added to the medication.

The Panel reviewed a study by Garrity, Halliday, and Glassman (Ref. 13), in which the authors reported very satisfactory results using 2 percent acetic acid in propylene glycol to prevent "swimmer's ear." The investigators observed 816 campers in two summer camps. The campers were divided into control and treatment groups. Those in the control group received no medication in their ears (although in the second camp, 190 subjects with less than 6 treatments out of a possible 24 during a 2-week stay were included in the control group). Campers in the treatment group were to receive two drops of the drug prophylactically in each ear, morning and evening. The investigators reported that in the first camp the prophylactic treatment prevented the occurrence of swimmer's ear in the treated group (no cases of swimmer's ear were reported in 31 subjects). In the untreated group, 3 out of 56 subjects developed swimmer's ear. In the second camp it was reported that none of the 462 subjects in the treated group developed swimmer's ear. In the control group, 3 out of 267 subjects developed swimmer's ear.

The agency has reviewed an additional study on prevention of swimmer's ear in campers. Heilig, Heilig, and Glassman (Ref. 14) did a 2- year study (two 46- to 47-day summer camping seasons) with followup of 400 children in a camp with over 10,000 swimming pool exposures. The authors stated that because of the high density of campers using a pool that was inadequate to handle the swimming load, there was a history of an unusually high incidence of swimmer's ear in the camp (approximately 30 cases occurred annually over several years). A solution of 2 percent acetic acid in propylene glycol was used in the study. Subjects were assigned into groups and treated (or not treated) as in the study by

Garrity, Halliday, and Glassman (Ref. 13) above.

During the first summer, the investigators reported that 2 out of 246 campers in the treated group developed swimmer's ear, compared with 10 out of 246 campers in the control group. During the following summer, 4 out of 221 campers developed swimmer's ear in the treated group compared with 14 out of 202 in the control group. The authors reported that a followup 3 years later revealed that the prophylactic program had been discontinued and that the number of swimmer's ear cases was again increasing. For this reason, during a third and final summer camp period. supervised instillation of the product containing 2 percent acetic acid in propylene glycol was begun in a portion of the camp population.

The results showed that 21 of 83 untreated subjects (25.3 percent) developed swimmer's ear, and 1 of 54 campers (1.9 percent) who were treated prophylactically developed swimmer's ear. After comparing these results with the number of swimmer's ear cases that had occurred during the first and second camp periods of the same year when no prophylactic treatment was given, the authors reported that the treatment regimen was successful. During the first camp period, 7 campers out of 90 (7.8 percent) developed swimmer's ear. During the second camp period, 28 campers out of 139 (20.1 percent) developed swimmer's ear.

The data submitted by the comment consisted of a study in which 25 subjects were treated prophylactically with three drops of an aqueous solution of 2 percent acetic acid in the left ear every night (Ref. 1). The right ear served as a control and received no drug treatment. The purpose of the study was to demonstrate that 2 percent acetic acid in water prevented swimmer's ear. The results indicated that 7 subjects developed external otitis in the right ear and that 18 subjects did not develop external otitis. No adverse reactions developed. No other details of the study were given.

The agency concludes that the data that were reviewed by the Panel on the bactericidal effect of acetic acid are supportive of the ability of acetic acid to inhibit the growth of bacteria. Because acetic acid creates an undesirable environment for bacteria, it is possible that the ingredient would be beneficial in preventing swimmer's ear. However, the data did not demonstrate this effect (Refs. 6 through 13).

The agency concludes that the studies conducted to demonstrate the effectiveness of 2 percent acetic acid in propylene glycol or in water in preventing swimmer's ear are inadequate because of deficiencies in the study design, lack of adequate baseline data and controls, and insufficient information in the studies (Refs. 1, 13, and 14). None of the studies contains information on the condition of the subjects' ears at baseline (before they entered the control or treatment groups), making it impossible to determine which subjects may have had symptoms of infection before being placed in the study. Also, the studies do not provide any evidence on whether the subjects had a previous history of swimmer's ear. Knowledge of a history of swimmer's ear is important because swimmer's ear infections are known to recur in susceptible individuals. Thus, the lack of data on the past history of the subjects as well as the lack of documentation on the condition of the subjects at baseline makes it impossible to determine whether control and treatment groups were comparable.

Furthermore, the agency notes that in the study by Garrity, Halliday, and Glassman (Ref. 13), assignment of patients to control and treatment groups was not randomized, and, in fact, all of the camp staff elected not to participate in the prophylactic program and thus were included in the control group. Additionally, 190 subjects who received less than 6 treatments were included in the control group, and those who received between 6 and 24 treatments (462 campers) were included in the treatment group. The agency questions the scientific validity of this manipulation. Moreover, in that same study, records indicate that in the second camp, the nurse responsible for overseeing the record keeping and administration of the medication frequently lost contact with campers who were on exercises in the wilderness. In view of these deficiencies, the agency does not consider this study adequately controlled, and the validity of any results reported is questioned.

The results obtained in the study by Heilig, Heilig, and Glassman (Ref. 14) are also unreliable because that study, like the previously discussed studies, lacks baseline data, has questionable comparability of control and treatment groups, lacks documentation on whether or not campers had symptoms of swimmer's ear when they arrived at camp, and does not provide adequate information on whether control and treatment groups had a comparable number of swimming pool exposures.

Furthermore, the agency notes that a prescription drug product containing 2

percent acetic acid in a propylene glycol vehicle was reviewed by the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group. That group evaluated the drug as probably effective for the treatment of otitis external caused by bacterial and fungal pathogens and possibly effective for the prevention of otitis external in swimmers and susceptible subjects. (See the Federal Register of September 18, 1970; 35 FR 14630.) In response to the notice, substantial evidence of effectiveness for the treatment indication was submitted, but data submitted to establish the effectiveness of the prophylactic indication failed to provide substantial evidence of effectiveness. Subsequently, in the Federal Register of July 19, 1974 (39 FR 26462), FDA reclassified the "possibly effective" indication to "lacking substantial evidence of effectiveness," and interested persons were afforded the opportunity to request a hearing on the matter. In response to the 1974 notice, data were submitted to establish the effectiveness of the prevention indication. These data included the studies by Garrity, Hallidy, and Glassman (Ref. 13) and by Heilig, Heilig, and Glassman (Ref. 14); however, the data were found inadequate to support the claim. On March 11, 1983, the manufacturer of the product filed a supplement to its NDA providing for the deletion of the prevention claim (Ref.

The study submitted by the comment (Ref. 1) does not contain information on how or under what conditions the study was conducted; how the presence or absence of swimmer's ear was determined; how subjects were selected and whether they were studied continuously for 2 years (the study is dated June 1980 through June 1982); whether subjects had a history of swimmer's ear; and whether they were exposed to similar conditions that might cause them to develop swimmer's ear. Because of the lack of details in the study, the meaning of the results cannot be determined. The agency's comments and evaluations of the data are on file in the Dockets Management Branch (Ref.

Based on the defects described above, the agency does not consider these studies adequate to establish that acetic acid should be classified as a Category I ingredient for the prevention of swimmer's ear. A study designed to measure a drug's ability to prevent an ear infection must contain provisions that ensure that (1) subjects are comparable with respect to the presence

or absence of the disease at the beginning of the study and (2) both control and treatment groups receive comparable exposure to conditions that might promote the development of swimmer's ear.

After consideration of the above data. the agency concludes that 2 percent acetic acid is safe for use in the ear. However, the data are inadequate to demonstrate the effectiveness of 2 percent acetic acid in distilled water or in propylene glycol for the prevention of swimmer's ear. Therefore, 2 percent acetic acid in distilled water or in propylene glycol is classified in Category III in this tentative final monograph. Adequate data to demonstrate the effectiveness of 2 percent acetic acid in preventing swimmer's ear must be submitted in order to upgrade this ingredient to monograph status.

References

- (1) Comment No. LET004, Docket No. 77N-0334, Dockets Management Branch.
- (2) Berkow, R., editor, "The Merck Manual," 14th Ed., Merck and Co., Inc., Rahway, NJ, p. 1946, 1982.
- Rahway, NJ, p. 1946, 1982. (3) Goodhill, V., "Diseases, Deafness, and Dizziness," Los Angeles, p. 286, 1979.
- (4) "Boies's Fundamentals of Otolaryngology," 5th Ed., W.B. Saunders Co., Philadelphia, p. 182, 1978.
- (5) "Handbook of Nonprescription Drugs," 7th Ed., American Pharmaceutical Association, Washington, pp. 406-407, 1982.
- (6) Pertinent pages of the Interim Working Papers of the Topical Analgesic, Antirheumatic, Otic, Burn, Sunburn Treatment and Prevention OTC Drug Review Panel, OTC Volume 06CTFM, Dockets Management Branch.
- (7) Summary Minutes of the Topical Analgesic, Antirheumatic, Otic, Burn, Sunburn Treatment and Prevention OTC Drug Review Panel, July 12 and 13, 1973, November 18 and 19, 1976, February 23 and 24, 1977, and May 25 and 26, 1977, Dockets Management Branch.
- (8) Osol A., editor, "Remington's Pharmaceutical Sciences," 16th ed., Mack Publishing Co., Easton, PA, pp. 1256–1257, 1980.
- (9) Ochs, I.L., "Use of Vinegar as an Antibiotic in the Treatment of Chronic Middle Ear Disease," *Archives of* Otolaryngology, 52:935–941, 1950.
- (10) Jones, E.H., and P.G. McLain, "Does Acid pH Inhibit Bacterial Growth in the External Ear Canal?," The Laryngoscope, 71-028-028 1081
- 71:928–936, 1961. (11) Ochs, I.L., "External Otitis," *Medical Times*, 88:579–581, 1960.
- (12) Goffin, F.B., "pH as a Factor in External Otitis," *The New England Journal of Medicine*, 268:287–289, 1963.
- (13) Garrity, J.D., T.C. Halliday, and J.M. Glassman, "Prevention of Swimmer's Ear by Simple Prophylactic Regimen," Current Therapeutic Research, 16:437–441, 1974.

(14) Heilig, D., M.C. Helig, and J.M. Glassman, "Prophylactic Use of a Topical Non-Aqueous Acetic Acid Medication for the Prevention of Otitis Externa (Swimmer's Ear): A Two-year Study with Follow-up," Current Therapeutic Research, 26:862-873, 1979.

(15) Letter from R.D. Frawley, Carter-Wallace, Inc., to C. Kimbrough, FDA, OTC Volume 06CTFM, Dockets Management

(16) Letter from W.E. Gilbertson, FDA, to T.H. Pope, Jr., coded LET009, Docket No. 77N-0334, Dockets Management Branch.

2. One comment submitted data on a formula containing 5 percent anhydrous glycerin and 95 percent isopropyl alcohol and stated that this formula is safe and effective "for prevention of swimmer's ear and treatment of waterclogged ears" (Ref. 1). The comment requested that the monograph be amended to allow those claims for products containing the two ingredients. In addition, the comment expressed concern about the agency's reclassification of glycerin from Category I to Category III in the tentative final monograph. The comment believed that, although the evidence in support of the effectiveness of glycerin may not suffice for approval of a new drug application, the evidence is of the same caliber as that found sufficient for other OTC drug ingredients, such as eugenol for the relief of toothache (47 FR 22728).

The agency has determined that the submitted data demonstrate the safety of the combination of 5 percent anhydrous glycerin and 95 percent isopropyl alcohol, but do not provide sufficient evidence of the effectiveness of these ingredients as a topical otic drug product "for the prevention of swimmer's ear" or the "treatment of water-clogged ears." Both an in vitro study and a clinical study were submitted to demonstrate the efficacy of this product in drying excess moisture in the ears (Ref. 1). In the vitro study, known weights of water were placed in petri dishes and varying amounts of the product were then added to the water. The petri dishes were left for 5 minutes covered (serving as a control) and uncovered in a 37° C incubator (to simulate the temperature of the outer ear canal). The results indicated a higher percentage of moisture lost in the uncovered petri dishes when compared with the covered petri dishes. Although these data are supportive, an in vitro study alone cannot substitute for a welldesigned clinical study to establish effectiveness.

In the clinical study, both ears of 49 patients were irrigated with water. The investigators determined the amount of water in the ears by tactilely palpating and visually inspecting the ears. A score of 0 (maximum wetness) to 5 was assigned depending on the degree of wetness of the ear. Following irrigation and scoring, the right ear of each patient received 4 or 5 drops of the product; the left ear was not treated with a drug, and served as a control. The patients' comments regarding any sensations in the ears were recorded. At the end of 5 minutes the ears of each patient again were visually inspected and palpated to determine the amount of water remaining in the ear. The results indicated that 5 percent anhydrous glycerin in 95 percent isopropyl alcohol was successful in drying more than 50 percent of the water in the ears of 42 out of 49 patients within a 5-minute period.

This clinical study provides some evidence of the product's effectiveness in drying water in the ear; however, this study did not state clearly that the test subjects had the symptoms of waterclogged ears. The ears of the test subjects were not randomized (all right ears were drug treated) and the study was not blinded. As a result, the determination of the product's effectiveness by the investigators may have been biased. The agency believes that another well-controlled clinical study is necessary to demonstrate the effectiveness of the product to help dry water in the ears or to help relieve the discomfort of water-clogged ears by drying excess water. The agency encourages the use of objective measurements to determine the decrease in the amount of water in the ears and subjective measurements to determine the decrease in the patient's degree of discomfort and to measure the relief of discomfort. The agency also believes that more than one observation at the end of a 5-minute period is necessary to evaluate the effectiveness of the product.

In addition, the study was not appropriately designed to demonstrate a claim of "prevention of swimmer's ear." The results did not show prevention of, or a reduction in, the incidence of swimmer's ear in a susceptible target population (i.e., persons with a history of recurrent swimmer's ear). (See

comment 1 above.)

In the submission, the two ingredients are claimed to be a combination product, yet the data did not show the effectiveness of each ingredient alone. If therapeutic claims are made for both the anhydrous glycerin and the isopropyl alcohol, then each ingredient must be tested alone and also in combination to demonstrate the effectiveness of the combination. However, if glycerin functions only as a vehicle (and the need for it as a vehicle is shown) and no claims are made for it as an active

ingredient, additional testing would not be required for this ingredient.

The agency believes that a claim of "prevention of swimmer's ear" is an acceptable OTC drug claim; however, adequate data must be provided to demonstrate the effectiveness of any ingredient(s) making such a claim. The agency acknowledges that the term "water-clogged ears" is not a recognized clinical entity and is not a term found in textbooks. However, the agency believes that consumers use the term "water-clogged ears" to refer to the temporary retention of water in the ears after swimming, showering, washing the hair, bathing, etc. It is well recognized that the retention of water in the ears is annoying and uncomfortable and can interfere with hearing. Some people experience a sensation of fullness or hearing impairment after getting water in the ear canal. Therefore, the agency believes that a claim such as "helps relieve the discomfort of water-clogged ears by drying excess water" would be acceptable because it relates to the relief of the symptoms described above. The agency believes that the phrase "helps dry water in the ears" or "helps relieve the discomfort of water-clogged ears by drying excess water" should be used in labeling instead of the comment's suggested phrase "treatment of water-clogged ears." The former phrases are more specific and better define the intended pharmacologic action of the drug. Therefore, the agency is proposing both of these claims in this tentative final monograph.

The agency is also proposing that the combination of 5 percent anhydrous glycerin and 95 percent isopropyl alcohol "for the prevention of swimmer's ear" and "for the drying of water in the ears" or "to help relieve the discomfort of water-clogged ears by drying excess water" be placed in Category III in this tentative final monograph. Adequate data must be submitted to demonstrate the efficacy of these ingredients for these proposed

In response to the comment's concern about the reclassification of glycerin to Category III in the earlier tentative final monograph (47 FR 30014), the agency notes that that reclassification concerns glycerin as an earwax removal aid, not as an ingredient for the prevention of swimmer's ear or the drying of water in the ears. Glycerin and isopropyl alcohol for these conditions were not classified by the Panel in its report or by the agency in the tentative final monograph. Eugenol was classified by the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products as a

Category I toothache relief agent in the advance notice of proposed rulemaking for OTC drug products for the relief of oral discomfort, published in the Federal Register of May 25, 1982; 47 FR 22712. At present, the agency cannot address the comment's statement that the supporting evidence for glycerin is comparable to that of eugenol because the agency has not completed its review of the Dental Panel's recommendations on relief of oral discomfort drug products.

The agency's comments and evaluation of the data are on file in the Dockets Management Branch (Refs. 2 and 3)

References

(1) Comment No. C00007, Docket No. 77N-0334, Dockets Management Branch.

(2) Letter from W.E. Gilbertson, FDA to H.W Gordon, Commerce Drug Co., Inc., coded LETS006, Docket No. 77N-0334, Dockets Management Branch.

(3) Letter from W.E. Gilbertson, FDA to H.W. Gordon, Commerce Drug Co., coded LET010, Docket No. 77N-0334, Dockets Management Branch.

II. The Agency's Tentative Conclusions on OTC Topical OTIC Drug Products

A. Summary of Ingredient Categories and Testing of Category III Conditions.

1. Summary of ingredient categories. The agency has reviewed the submitted data on 2 percent acetic acid and the combination of 5 percent anhydrous glycerin and 95 percent isopropyl alcohol used for the prevention of swimmer's ear and 5 percent anhydrous glycerin and 95 percent ispropyl alcohol used for the drying of water in the ears or for the relief of the discomfort of water-clogged ears by drying excess water, as well as other data and information available at this time, and is classifying these ingredients in Category III for these uses. (See comments 1 and 2 above.) Adequate data must be submitted to the agency in order to demonstrate the effectiveness of these ingredients for these claims. The agency is aware that topical otic drug products containing other ingredients for which no data were submitted to the Panel or to the agency are also marketed OTC for the prevention of swimmer's ear. The agency invites comments and the submission of data on any ingredient that is promoted for any claim related to the prevention of swimmer's ear, the drying of water in the ears, or the relief of the discomfort of water-clogged ears by drying excess water. If no data are submitted or the data are insufficient to establish the safety and effectiveness of any ingredient for these conditions, then any ingredient marketed OTC will be classified as a nonmonograph condition

in a final rule, and upon the effective date of that final rule will require an approved NDA before continuing marketing.

2. Testing of Category III conditions. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any topical otic drug ingredient for the prevention of swimmer's ear, the drying of water in the ears, or the relief of the discomfort of water-clogged ears by drying excess water, or for any condition included in the review by following the procedures outlined in the agency's policy statement published in the Federal Register of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Recommendations.

FDA has considered the comments and other revelant information and has tentatively reached the following conclusions:

1. The agency is proposing that 2 percent acetic acid in distilled water or in propylene glycol and the combination of 5 percent anhydrous glycerin and 95 percent isopropyl alcohol be placed in Category III for the prevention of swimmer's ear. The agency is also proposing a Category III classification for the combination of 5 percent anhydrous glycerin and 95 percent isopropyl alcohol for the drying of water in the ears or for the relief of the discomfort of water-clogged ears by drying excess water.

2. Although no ingredients for the prevention of swimmer's ear, the drying of water in the ears, or the relief of the discomfort of water-clogged ears by drying excess water have been determined to be generally recognized as safe and effective and not misbranded, the agency is proposing labeling for these products in this tentative final monograph in the event that new data are submitted that result in the upgrading of any ingredient to monograph status. The proposed doses in the directions are based on the directions of some of the currently marketed swimmer's ear and ear waterdrying products. However, if acceptable new data support different doses, the final monograph will reflect the new data.

3. The warnings in this tentative final monograph are based on (1) the warnings proposed for earwax removal

aids in the tentative final monograph for OTC topical otic drug products but which are also applicable to products for the prevention of swimmer's ear and relief of water-clogged ears, (2) currently marketed products, and (3) the discussion of swimmer's ear drug products in the Panel's interim working papers. Additionally, the agency is proposing other warnings to provide for the safe and proper use of these drug products.

4. In the event that any ingredient for the prevention of swimmer's ear, the drying of water in the ears, or the relief of the discomfort of water-clogged ears by drying excess water is upgraded to monograph status, the agency is amending the tentative final monograph for topical otic drug products by revising the existing heading of § 344.10 ("Topical otic active ingredient") to read "Earwax removal aid active ingredient" and revising the existing heading of § 344.50 ("Labeling of topical otic drug products") to read "Labeling of earwax removal aid drug products." The agency also proposes to add definitions for the terms "water-clogged ears," "ear waterdrying aid," "swimmer's ear," and "swimmer's ear prevention aid," in § 344.3 (c), (e), and (f), respectively, and to add new § 344.12 entitled "Ear waterdrying aid active ingredients," new § 344.14 entitled "Swimmer's ear prevention aid active ingredients," new § 344.52 entitled "Labeling of ear water-drying aid drug products," and new § 344.54 entitled "Labeling of swimmer's ear prevention aid drug products."

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule on OTC topical otic drug products to include labeling for the prevention of swimmer's ear, the drying of water in the ears, and the relief of the discomfort of water-clogged ears by drying excess water, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act,

Public Law 96-354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC topical otic drug products for the prevention of swimmer's ear, the drying of water in the ears, and the relief of the discomfort of water-clogged ears by drying excess water is not expected to pose such an impact on small businesses. Therefore, the agency certified that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC topical otic drug products for the prevention of swimmer's ear, the drying of water in the ears, or the relief of the discomfort of water-clogged ears by drying excess water. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC topical otic drug products for the prevention of swimmer's ear, the drying of water in the ears, or the relief of the discomfort of water-clogged ears by drying excess water should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on topical otic drug products for these conditions, a period of 120 days from the date of publication of this proposed rulemaking in the Federal Register will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In the Federal Register of April 22, 1985 (50 FR 15810) the agency proposed to change its "exclusivity" policy for the labeling of OTC drug products that has existed during the course of the OTC drug review. Under that policy, the agency had maintained that the terms used in an OTC drug product's labeling were limited to those terms included in a final OTC drug monograph.

In the Federal Register of May 1, 1986 (51 FR 16258), the agency published a final rule changing the exclusivity policy and establishing three alternatives for stating the indications for use in OTC drug labeling. Under the final rule, the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED uses": (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED uses": plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All required OTC drug labeling other than indications for use (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under an OTC drug monograph. The proposed rule in this document is subject to the final rule revising the exclusivity policy.

Interested persons may, on or before September 29, 1986, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before November 28, 1986. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

Interested persons, on or before July 30, 1987, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before September 30,

1987. These dates are consisent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA-305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on (September 30, 1987). Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the Federal Register, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 344

OTC drugs; Topical otic drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Administrative Procedure Act, and under 21 CFR 5.11, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 344 as proposed in the Federal Register of July 9, 1982, 47 FR 30012, as follows:

PART 344—TOPICAL OTIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 344 would continue to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

2. In Subpart A, § 344.3 is amended by adding new paragraphs (c), (d), (e), and (f), to read as follows:

§ 344.3 Definitions.

(c) Water-clogged ears. The retention of water in the external ear canal thereby causing discomfort and a sensation of fullness or hearing impairment.

(d) Ear water-drying aid. A drug used in the external ear canal to help dry water-clogged ears.

(e) Swimmer's ear. A bacterial or fungal infection of the skin lining the external auditory canal that may occur in susceptible individuals following the retention of water in the ears, also known as external otitis.

(f) Swimmer's ear prevention aid. A drug used in the external ear canal to aid in the prevention of swimmer's ear (external otitis).

3. In subpart B, by revising the section heading of § 344.10 and by adding new § § 344.12 and 344.14 to read as follows:

§ 344.10 Earwax removal aid active ingredient.

§ 344.12 Ear water-drying aid active ingredients. [Reserved]

§ 344.14 Swimmer's ear prevention aid active ingredients. [Reserved]

4. In subpart C, by revising the section heading of § 344.50 and by adding new §§ 344.52 and 344.54 to read as follows:

§344.50 Labeling of earwax removal drug products.

§ 344.52 Labeling of ear water-drying aid drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "ear water-drying aid."

(b) Indications. The labeling of the product states, under the heading "Indications," one or both of the following: "Helps dry water in the ears," or "Helps relieve the discomfort of water-clogged ears by drying excess water." Other truthful and nonmisleading statements, describing

only the indications for use that have been established and listed above, may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) "Do not use if you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy; consult a doctor."

(2) "Do not use if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor."

(3) "Avoid contact with the eyes."

(4) "Discontinue use and consult a doctor if undue irritation or sensitivity occurs."

(5) For products containing alcohol. "Keep away from fire or flame."

(d) Directions. Apply 4 or 5 drops in each ear when water remains in the ear after swimming, showering, or bathing.

after swimming, showering, or bathing.
(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

§ 344.54 Labeling of swimmer's ear prevention aid drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "swimmer's ear prevention aid."

(b) Indications. The labeling of the product states, under the heading "Indications," the following: "Aids in the prevention of swimmer's ear (external otitis)" [which may be followed by the

appropriate term(s): "by helping to dry moisture in the ears" or "by restoring the normal acidity of the ears"]. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed above, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the prohibitions in section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

under the heading "Warnings":
(1) "Do not use this produce unless you have a previous history of swimmer's ear."

(2) "Do not use if you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy; consult a doctor."

(3) "Do not use if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor."

(4) "Avoid contact with the eyes."

(5) "Discontinue use and consult a doctor if undue irritation or sensitivity occurs."

(6) For products containing alcohol. "Keep away from fire or flame."

(d) Directions. Apply 4 or 5 drops in each ear after swimming, showering, or bathing or as directed by a doctor.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

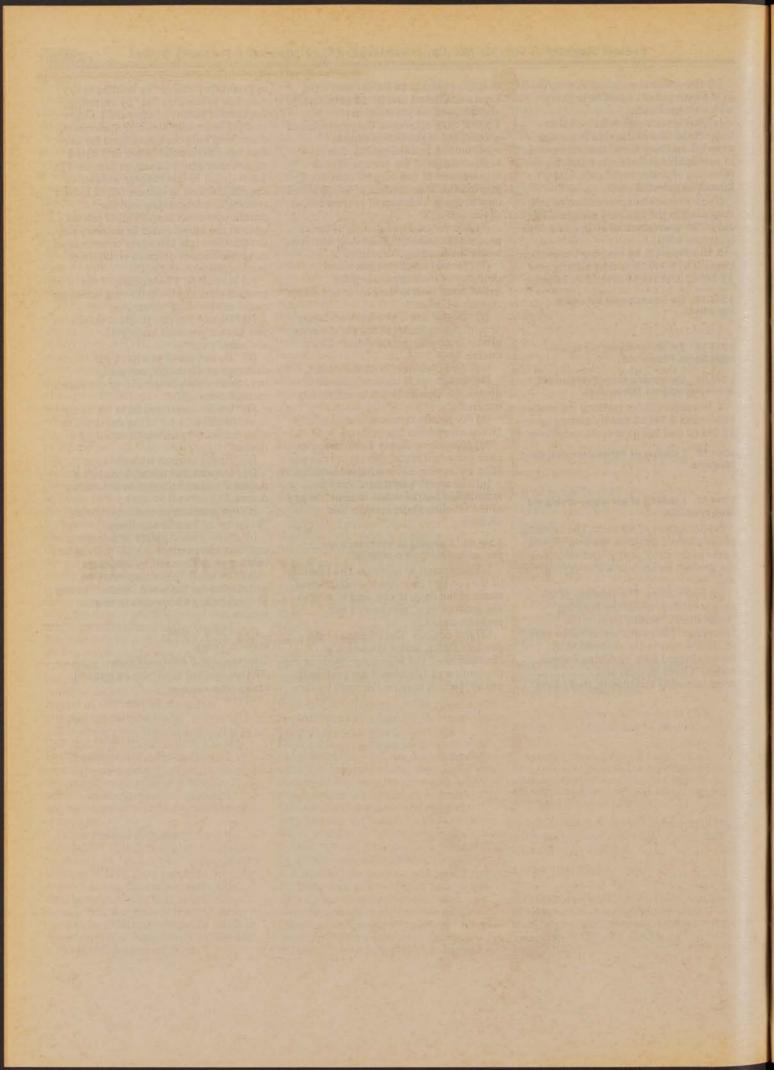
Dated: May 3, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86–17041 Filed 7–29–86; 8:45 am]

BILLING CODE 4160–01-M





Wednesday July 30, 1986

Part VI

Department of the Interior

Fish and Wildlife Service

50 CFR Part 20

Migratory Bird Hunting; Proposed Migratory Bird Hunting Regulations on Federal Indian Reservations, Indian Territory, and Ceded Lands; Proposed Rule



DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

Migratory Bird Hunting; Proposed Migratory Bird Hunting Regulations on Federal Indian Reservations, Indian Territory, and Ceded Lands

AGENCY: U.S. Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: This document proposes special migratory bird hunting regulations on Federal Indian reservations, Indian Territory, and ceded lands for the 1986-87 hunting season. This season will commence on September 1, 1986.

The U.S. Fish and Wildlife Service (hereinafter the Service) annually prescribes migratory bird hunting regulations frameworks to the States. This rule proposes migratory bird hunting regulations to be established for certain tribes on Federal Indian reservations, Indian Territory, and ceded lands in the 1986-87 hunting

DATE: The comment period for these proposed regulations will end August 14,

ADDRESSES: Address comments to: Director (FWS/MBMO), U.S. Fish and Wildlife Service, Room 536, Matomic Building, Washington, DC 20240. Comments received on these proposed hunting regulations and tribal proposals will be available for public inspection during normal business hours in Room 536, Matomic Building, 1717 H Street, NW, Washington, DC. The Service's biological opinions resulting from its consultation under section 7 of the Endangered Species Act are available for public inspection in or are available from the Office of Endangered Species and the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Rollin D. Sparrowe, Chief, Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Department of the Interior, Washington, DC 20240 (202-254-3207).

SUPPLEMENTARY INFORMATION: The Migratory Bird Treaty Act of July 3, 1918 (40 Stat. 755; U.S.C. 703 et seq.) authorizes and directs the Secretary of the Interior, having due regard for the zones of temperature and for the distribution, abundance, economic value, breeding habits, and times and lines of flight of migratory game birds, to determine when, to what extent, and by what means such birds or any part, nest or egg thereof may be taken, hunted, captured, killed, possessed, sold, purchased, shipped, carried, exported or transported.

In the December 5, 1985, Federal Register (50 FR 49870-49871) the Service requested proposals from Indian tribes that wished to establish special migratory bird hunting regulations for the 1986-87 hunting season, under the interim guidelines published for this purpose on September 3, 1985 (at 50 FR 35762-35765). The guidelines were developed in response to tribal requests for Service recognition of their reserved hunting rights, and for some tribes, recognition of their full wildlife management authority to regulate hunting by both tribal and nontribal members on their reservations. The guidelines include possibilities for: (1) On-reservation hunting (including Indian Territory) by both tribal and nontribal members, with hunting by nontribal members on some reservations to take place within Federal frameworks, but on dates different from those selected by surrounding State(s); (2) on-reservation hunting (including Indian Territory) by tribal members only, outside of usual Federal frameworks for season dates and length, and for daily bag and possession limits; and (3) off-reservation hunting by tribal members on ceded lands, outside of usual framework dates and season length, with some added flexibility in daily bag and possession limits. In all cases, the regulations established under the guidelines would have to be consistent with the closed season requirement mandated by the 1916 Migratory Bird Treaty with Canada. The guidelines are capable of application to those tribes that have recognized reserved hunting rights on Federal Indian reservations (including Indian Territory) and ceded lands. They also apply to establishing migratory bird hunting regulations for nontribal members on reservations and Indian Territory where tribes have gained full wildlife management authority by judicial decisions or other means. In cases where the scope of tribal management authority is unclear, the Service, on request, will consult with tribal and State officials, with the aim of reaching mutual agreement on tribal hunting regulations. The Service also will consult jointly with tribal and State officials in the State(s) where tribes may wish to establish special hunting regulations for tribal members on ceded

Before developing the guidelines, the Service reviewed available information on the current status of migratory bird hunting on Federal Indian reservations and evaluated the impact that adoption of the guidelines likely would have on migratory birds. The Service has concluded that the size of migratory bird harvest by tribal members hunting on their reservations is too small to have significant impact on the migratory bird resource when compared with the much larger off-reservation sport harvest by non-Indians. The major area of concern relates to hunting seasons for nontribal members on dates that are within Federal frameworks, but that are different from those established by the State(s) in which a Federal Indian reservation is located. A large influx of nontribal hunters onto a reservation at a time when the season is closed in the surrounding State(s) could result in adverse harvest impacts for one or more migratory bird species. The guidelines make such an event unlikely, however, because tribal proposals must include details on the harvest anticipated under the requested regulations; methods that will be employed to measure or monitor harvest (bag checks, mailquestionnaries, etc.); steps that will be taken to limit level of harvest where it could be shown that failure to limit such harvest would impact seriously on the migratory bird resource; and tribal capabilities to establish and enforce migratory bird hunting regulations. Based on a review of tribal proposals, the Service may require modifications. and regulations may be established experimentally, pending evaluation and confirmation of harvest information obtained by the tribes.

The Service recognizes that as the guidelines are tested over time, some changes may be needed, and they should not be viewed as inflexible. Nevertheless, the Service believes that they provide reasonable and necessary standards to accommodate the reserved hunting rights and management authority of Indian tribes while ensuring that the migratory bird resource receives necessary protection.

Review of Comments Received on **Notice Requesting Hunting Season Proposals from Indian Tribes**

The Service received the following four comments in response to the December 5, 1985, Federal Register notice requesting tribal proposals: 1. Wildlife Legislative Fund of America

Comments. In a December 20, 1985, letter, Mr. James H. Glass, President, objected to special hunting privileges for Indians, and he urged the Service to strive to bring hunting regulations into conformity so that Indians and nonIndians are treated as equals. He stated his belief that it is discriminatory for a citizen who claims a fraction of Indian blood to have greater hunting privileges than non-Indians, and he asked the Service to add the following two items to the requirements for details needed in tribal proposals: (1) Claimed legal basis for application of special regulations different from those in effect for other citizens, and (2) justification for application of regulations different from those otherwise applicable to the flyway. Mr. Glass felt that these additions will help clarify the reasons for the Service's differential treatment of Indians and non-Indians in establishing hunting regulations.

Response. The Service recognizes that special hunting regulations for Indians are viewed as discriminatory by some non-Indians. Nonetheless, the Service believes it is appropriate to accommodate the reserved hunting rights and wildlife management authority of Indian tribes to the degree that this accommodation is compatible with migratory bird conservation.

The fact that a person claims Indian blood does not qualify him for special hunting rights. He also must be a member of a tribe that has such rights. and these rights apply only to the tribe's reservation or other lands, and, in some cases, lands that were ceded by treaty. The guidelines described earlier make it clear that hunting regulations outside of Federal frameworks are available only to members of tribes that have recognized hunting rights. While there are exceptions, most tribes on Federal Indian reservations have such rights. For this reason, the Service sees no need to require tribes to document the legal basis for their on-reservation hunting rights. However, the Service will carefully scrutinize tribal requests for special hunting regulations on ceded lands. Thus far, only the Great Lakes Indian Fish and Wildlife Commission (representing various Chippewa Indian Tribes) has requested such regulations for off-reservation hunting of migratory game birds.

In regard to Mr. Glass' request that tribes justify hunting regulations different from those applicable to flyways, the Service notes that one of the guidelines provides for the continuation of sustenance harvest of waterfowl and other migratory game birds on reservations where it is a customary practice. The Service does not oppose this harvest, provided it does not take place during the closed period required by the 1916 Canadian Migratory Bird Treaty, and it is not so large as to adversely affect the status of

the migratory bird resource. The Service has offered to consult with tribes that wish to reach a mutual agreement on their hunting seasons.

It should again be stressed that hunting of migratory birds outside of Federal frameworks is appropriate only for members of tribes with recognized reserved hunting rights. The Service will continue to consider requests from tribes with full wildlife management authority that wish to establish migratory bird hunting regulations on dates that may differ from those established by the State(s) in which the reservation is located. However, the season dates must be within the final frameworks approved for the States within the flyway, and all other Federal regulations apply to nontribal members. Tribes requesting different season dates must include details on anticipated harvest, and other information described earlier in this document. The Service desires to aid the tribes in their wildlife management programs; however, different season dates for nontribal hunters cannot be established if they are likely to result in an excessive harvest that would impact adversely on the migratory bird resource.

Generally, the Service believes that the migratory bird hunting regulations established by States in which Indian reservations are located provide necessary resource protection and appropriate hunting opportunity for nontribal members on the reservations. However, there may be exceptions. For instance, a tribe may wish to establish regulations that are somewhat more restrictive than those established elsewhere in the State.

2. Wisconsin Department of Natural Resources

Comments. Mr. C.D. Besadny,
Secretary, stated in a February 2, 1986,
letter that the process defined in the
December 5, 1985, Federal Register
notice is satisfactory to the State of
Wisconsin. He suggested, however, that
the Service require that a copy of the
tribal hunting season proposal be
submitted to the appropriate State for
informational purposes at the same time
it is sent to the Service.

Response. The Service will add this request in future Federal Register notices to tribes. As will be described later, the Wisconsin Department of Natural Resources also commented on a proposal from the Great Lakes Indian Fish and Wildlife Commission for off-reservation hunting by Chippewa Indians on ceded lands in the State.

3. White Earth Indian Reservation, White Earth, Minnesota

Comments. In a March 5, 1986, letter, Mr. Dwight Wilcox, Reservation Biologist, notified the Service that the tribe was evaluating the results of the 1985 hunting season and had not decided on tribal regulations to be established for the 1986 hunting season. More recently, on June 25, 1986, the tribe and Service reached an informal agreement on regulations for the upcoming hunting season.

Response. The Service notes that the White Earth Band of Minnesota Chippewa Indians was one of the first tribes to ask for Service recognition of the reserved hunting rights of its members. The Service is pleased that it was possible to use one of the guidelines to reach mutual agreement on tribal hunting regulations.

4. Upper Columbia United Tribes Fisheries Research Center, Cheney, Washington

Comments. On January 29, 1986, Ms. Margaret Brittingham, Wildlife Biologist, informed the Service that the Spokane Tribe will not request special hunting regulations now but may wish to establish such regulations for non-Indians on tribal lands in the 1987–88 hunting season. Ms. Brittingham asked to be notified when the Service publishes further information on this topic.

Response. The Service notes that while the guidelines do not specifically address on-reservation hunting by nontribal members on Indian lands only, tribes on most Federal Indian reservations have the authority to regulate all hunting on their lands. The Service will consider establishing special hunting regulations for nontribal members on tribal lands, provided the regulations are unlikely to result in excessive harvest.

Hunting Season Proposals From Indian Tribes and Organizations

The Service received requests from seven tribes and Indian organizations for special migratory bird hunting regulations for the 1986–87 hunting season. Five of them had special regulations in the 1985–86 hunting season.

The proposed regulations for the different tribes are shown below. It should be noted that this proposed rule, and a final rule to be published later in an August 1986, Federal Register, will include tribal regulations for both early and late hunting seasons. The early season begins on September 1 each year and includes species such as mourning doves and white-winged doves. The late season usually begins on or around October 1 and includes most waterfowl

species. The proposed frameworks for the 1986-87 early season regulations were published on July 3, 1986, (in 51 FR 24415-24425), and with one exception, all tribal requests for special regulations that would apply to species hunted under early season regulations are within these published frameworks. However, proposed late season frameworks will not be published until mid-August, and the final late season frameworks will not be published until well after the beginning of the early hunting season. Because final regulations for Indian tribes must be established by September 1, the proposed and final regulations for most tribal waterfowl seasons are described in relation to the season dates, season length, and limits that will be permitted when final waterfowl season frameworks are announced. For example, the daily bag and possession limits for ducks on most reservations in the Pacific Flyway are shown below as "Same as permitted Pacific Flyway States under final Federal frameworks." In some instances, specific proposed regulations are shown because they are almost certain to be within the final frameworks that will be established. An example is season dates and bag limits for Canada geese on the Navajo Indian Reservation.

It should be emphasized that migratory bird hunting regulations for nontribal members of Indian reservations cannot be more liberal than those permitted the States in which the reservations are located. Unless a tribe wishes to provide special protection to one or more species, requested special regulations in future proposals should be presented in the general manner described above. As discussed earlier, the final rule for tribes will provide specific season dates and bag limits for migratory bird species included in the early season regulations. Waterfowl regulations will be shown in a more general way, and the Service will notify affected tribes of season dates, bag limits, etc., as soon as they are established. No action is required by tribes that wish to observe the migratory bird hunting regulations established by the State in which a reservation is located.

1. Penobscot Indian Nation, Old Town, Maine

Last year, the tribe requested a general migratory bird hunting season for both tribal and nontribal members under regulations adopted by the State, and a sustenance season that would apply only to tribal members. The Service approved the sustenance season but requested that the tribe carefully

monitor the black duck harvest because of concern regarding its population status. The tribe confirmed that the black duck harvest was negligible in size.

In a January 22, 1986, proposal, the tribe again requested general and sustenance seasons on their Indian Territory, an area much larger than the reservation. The sustenance season would include only ducks, would begin on September 20 and end on November 30, and would permit Sunday hunting (not allowed under State regulations). The daily bag limit under sustenance regulations would be 4 ducks, with no more than 2 wood ducks or 2 black ducks. Where sustenance and general seasons coincide, the daily bag limit for any species or in total would be the larger of the two possible limits. The tribe asked that possession limits be waived in the sustenance season and that shooting hours extend from 1/2 hour before sunrise to 1 hour after sunset. The tribe agreed to observe all other migratory bird hunting regulations in effect in the 1986-87 hunting season. The Service intends to approve the tribal request. Since the tribe has shown that the sustenance harvest is too small to impact adversely on the black duck population, the Service does not believe it is necessary again to establish the season on an experimental basis. However, because of continuing concern regarding black ducks, the Service requests that the tribe continue to monitor size and species composition of the waterfowl harvest by both tribal and nontribal members. The Service notes that the tribe is aware of the insecure status of black ducks and will not have a sustenance season on the species if the State adopts a season-long closure on black ducks in the 1986-87 hunting season.

2. Navajo Nation, Navajo Indian Reservation, Window Rock, Arizona

In the 1985–86 hunting season, the Service established uniform migratory bird hunting regulations for both tribal and nontribal members on the Navajo Indian Reservation (in parts of Arizona, New Mexico, and Utah). The tribe has recognized full wildlife management authority on their reservation.

On February 4, 1986, the Navajo
Nation submitted a proposal in which
uniform regulations would be
established again on the reservation.
Certain details in the proposal were
clarified in a June 24, 1986, telephone
conversation. The Service notes that the
requested migratory bird hunting
regulations generally are more
restrictive than final Federal
frameworks permit for States in the

Pacific Flyway, and the Service therefore intends to establish the following tribal regulations for the 1986– 87 hunting season:

A. Ducks (including Mergansers)
Season Dates: October 11 through
November 30.

Daily Bag and Possession Limits;
Same as permitted Pacific Flyway States
under final Federal frameworks.
B. Canada Geese (Season closed on
other geese)

Season Dates: December 27 through January 4.

Daily Bag and Possession Limits: 2 daily. Possession limit 4. Season limit 5. C. Other Migratory Game Birds

1. Coots and Common Moorhens. Season Dates: October 11 through November 30.

Daily Bog and Possession Limits: Same as permitted Pacific Flyway States under final Federal frameworks.

2. Mourning Doves.

Season Dates: September 1 through September 30.

Daily Bag and Possession Limits: 12 daily. Possession Limit 24.

3. Band-tailed Pigeons.

Season Dates: September 1 through September 30.

Daily Bag and Possession Limits: 5 daily. Possession limit 10.

D. General Conditions. Tribal and nontribal members will comply with all basic Federal migratory bird hunting regulations in 50 CFR Part 20 regarding shooting hours and manner of taking. In addition, each waterfowl hunter 16 years of age or over must carry on his person a valid Migratory Bird Hunting and Conservation Stamp, or duck stamp, signed in ink across the face. Special regulations established by the Navajo Nation also apply on the reservation.

3. Jicarilla Apache Tribe, Jicarilla Indian Reservation, Dulce, New Mexico

The Jicarilla Apache Tribe has recognized full wildlife management authority on their reservation, and on February 6, 1986, requested a waterfowl season for both tribal and nontribal members that would begin on October 4 and end on November 30. The tribe did not request special regulations in the 1985–86 hunting season. In the proposal, the tribe indicated that the duck harvest is small on the reservation and that no geese were bagged in the 1985–86 hunting season. The tribe desires an October 4 opening because of early departure of resident and migrant ducks.

The Service does not object to the tribe's request, but notes that final Federal frameworks for the 1986–87 waterfowl hunting season will not be established until early September. The Service cannot authorize an opening

before the final framework beginning date but intends to approve an opening on October 4, or as near that date as possible. The Service also proposes to establish the same daily bag and possession limits on the reservation that will be approved for States in the Pacific Flyway. The Service will inform the tribe when final frameworks have been announced.

4. Colorado River Indian Tribes, Colorado River Indian Reservation, Parker, Arizona

At the request of tribal officials, the 1985-86 hunting regulations on the reservation were the same as those established for mourning doves, whitewinged doves, and waterfowl in California's Colorado River Zone. The tribes have full wildlife management authority, and the regulations applied to both tribal and nontribal members. The Service did not require that the regulations be experimental because the hunting seasons on the reservation were unlikely to result in a large influx of non-Indian hunters on dates when the season was closed in surrounding States.

In a June 16, 1986, letter the tribe requested essentially the same dove hunting regulations as in the 1985-86 season but proposed more liberal hunting regulations for ducks and geese. The Service notes that there was a major decline in the fall flight of waterfowl last year and, as a conservation measure, it was necessary to establish more restrictive hunting regulations. While some increase in waterfowl numbers is hoped for this year, it is unlikely that it will be possible to establish the more liberal hunting regulations that were prevalent before the 1985-86 hunting season. The Service, therefore, proposes again to establish the same season dates, season length, daily bag and possession limits, and other Federal migratory bird hunting regulations on the reservation that also will be established in the Colorado River Zone in California for mourning doves, white-winged doves, ducks, and geese. The regulations will apply to both tribal and nontribal members, and they will not be experimental. If this proposal is acceptable, the tribes will be notified as soon as the final regulations have been announced.

5. White Mountain Apache Tribe, Fort Apache Indian Reservation, Whiteriver, Arizona

In a proposal received on January 23, 1986, the Game and Fish Department of the White Mountain Apache Tribe requested special season dates for migratory bird hunting seasons that would apply to both tribal and nontribal members. In earlier correspondence, the

tribe had stressed that it has full wildlife management authority but did not submit a request for special hunting regulations in the 1985–86 hunting season.

The requested opening dates for all migratory game birds included in the proposal are within final Federal frameworks. However, the season lengths requested for waterfowl, mourning doves, coots and common moorhens (gallinules) are longer than likely will be permitted when final frameworks are established. The Service proposes to establish the following regulations on the Fort Apache Indian Reservation:

A. Ducks, including Mergansers
Season Dates: Begin continuous
season on October 18, 1986, with same
season length permitted Pacific Flyway
States under final Federal frameworks.

Daily Bag and Possession Limits: Same as permitted Pacific Flyway States under final Federal frameworks. B. Geese

Season Dates: Begin continuous season on November 15, 1986, with same season length permitted Pacific Flyway States under final Federal frameworks,

Daily Bag and Possession Limits:
Same as permitted Pacific Flyway States
under final Federal frameworks.
C. Other Migratory Game Birds

1. Coots and Common Moorhens.
Season Dates: Same as for ducks.
Daily Bag and Possession Limits:
Same as permitted Pacific Flyway States under final Federal frameworks.

2. Mourning Doves.

September 20, 1986 through October 11, 1986, and November 23, 1986, through January 9, 1987.

Daily Bag and Possession Limits September 20 through October 11, 1986:

12 mourning and white-winged doves daily in the aggregate, of which no more than 6 may be white-winged doves. Possession limit is 24 mourning and white-winged doves in aggregate, of which no more than 12 may be white-winged doves.

November 23, 1986, through January 9, 1987:

12 mourning doves only. Possession limit 24.

3. White-winged Doves.

Season Dates: September 20 through October 11, 1986.

Daily Bag and Possession Limits: 12 white-winged and mourning doves daily in the aggregate, of which no more than 6 may be white-winged doves.

Possession limit is 24 white-winged and mourning doves in aggregate, of which no more than 12 may be white-winged doves.

4. Band-tailed Pigeon.

Season Dates: October 11 through November 9, 1986.

Daily Bag and Possession Limits: 5 daily. Possession limit 10.

Special Band-tail Permit: Band-tailed pigeon hunters shall have in their possession a 1986 Special Band-tail Permit which may be obtained without charge at offices of the White Mountain Game and Fish Department or any license dealer after August 1, 1986.

5. Sandhill Cranes and Common (Wilson's) Snipe: Season closed.

D. General Conditions. Tribal and nontribal hunters will comply with all basic Federal migratory bird hunting regulations in 50 CFR Part 20 regarding shooting hours and manner of taking. In addition, each waterfowl hunter 16 years of age or over must carry on his person a valid Migratory Bird Hunting and Conservation Stamp, or duck stamp, signed in ink across the face. Special regulations established by the White Mountain Apache Tribe also apply on the Fort Apache Reservation.

Approval of these proposed hunting regulations in a later final rule is contingent on submission by the White Mountain Apache Tribe of details required in proposals, i.e., anticipated harvest; methods that will be employed to measure or monitor harvest; steps that will be taken to limit level of harvest, where it could be shown that failure to limit such harvest could impact seriously on the migratory bird harvest; and tribal capabilities to establish and enforce migratory bird hunting regulations. The details described above and written approval of these proposed regulations by an authorized tribal official must be received by the Service no later than August 14, 1986. The necessary information should be mailed to the location shown earlier under ADDRESSES. The Service also will consider alternative hunting season dates, provided they are within final Federal frameworks, are supported by evidence that makes it unlikely that the regulations would cause a harvest that would have adverse impacts on the resource, and are received by the closing date shown above. 6. Great Lakes Indian Fish and Wildlife Commission, Odanah, Wisconsin

Last year, following consulation with the Wisconsin Department of Natural Resources, (WDNR) and the Great Lakes Indian Fish and Wildlife Commission (GLIFWC), the Service approved special regulations for off-reservation late September hunting of waterfowl by Chippewa Indians on ceded lands in Wisconsin. Because of WDNR concern regarding possible displacement of waterfowl due to disturbance, the tribal season was closed 5 days before the regular State waterfowl season opened, and the regulations were established experimentally, pending evaluation of size of harvest by the GLIFWC and a cooperative assessment of possible waterfowl displacement. The waterfowl harvest was not expected to be large, and this proved to be the case. The estimated September harvest by 42 tribal members was 19 Canada geese and 96 ducks. There was no indication of waterfowl displacement caused by the early hunting.

On April 3, 1986, the GLIFWC submitted a proposal for off-reservation hunting in 1986 by Chippewa Indians on ceded lands in the western portion of Michigan's Upper Peninsula, as well as on ceded lands in Wisconsin. The proposal was revised on May 15, 1986. In the proposal, the GLIFWC requested earlier Canada goose hunting seasons and asked that the 5-day closure that was in effect last year be removed. Michigan and Wisconsin officials requested that the tribes delay their proposed Canada goose season because of possible adverse impacts on local breeding populations. The WDNR continued to be concerned about possible waterfowl displacement and asked the tribes to retain the closure before the beginning of the regular State waterfowl hunting season.

As a result of recent consultations led by Service representatives from the Twin Cities, Minnesota, Regional Office, general agreement was reached with GLIFWC and State officials on proposed regulations for the off-reservation hunting seasons. In Michigan, the Service proposes to provide some flexibility in Canada goose bag limits during the regular State waterfowl season. In Wisconsin, the Service proposes similar flexibility in Canada goose bag limits with a September 25 opening date. The Service proposes to approve the requested continuous duck season in Wisconsin. However, in recognition of the WDNR concerns, the Service will require that hunter numbers, duck harvest, and waterfowl distribution are monitored at popular Wisconsin hunting areas in the ceded lands region during the portion of the duck season that precedes the Statewide duck season. If waterfowl distribution in certain locales is significantly altered because of Indian hunting pressure, as agreed upon by the Service, the GLIFWC, and the WDNR, those locales will be closed in 48 hours by emergency tribal order until the Statewide season opens. The regulations, if established, will be experimental in both Michigan

and Wisconsin, and the GLIFWC will estimate the species composition and size of harvest by tribal members in the same manner as was employed in the 1985–86 hunting season. The proposed hunting regulations are as follows:

A. Ducks

Wisconsin Zone:

Season Dates: Begin 15 days prior to opening of regular State duck season. End with closure of State duck season.

Daily Bag and Possession Limits: Same as permitted Wisconsin under final Federal frameworks.

Michigan Zone:

Same dates, season legnth, and daily bag and possession limits permitted Michigan under final Federal frameworks.

Special Scaup-Only Season: Same dates, season length, and daily bag and possession limits permitted Wisconsin and Michigan under final Federal frameworks.

B. Geese

Wisconsin Zone:

Canada Geese.

Season Dates: Begin September 25. End October 31.

Daily Bag and Possession Limits: 3 daily. Possession limit 6.

Other Geese (snow geese, blue geese, white-fronted geese). Same dates, season length, and daily bag and possession limits permitted Wisconsin under final Federal frameworks.

Michigan Zone: Canada Geese.

Season Dates: Same dates and season length permitted Michigan under final Federal frameworks.

Daily Bag and Possession Limits: 3 daily. Possession limit 6.

Other Geese (snow geese, blue geese, white-fronted geese). Same dates, season length, and daily bag and possession limits permitted Michigan under final Federal frameworks.

C. Other Migratory Game Birds

Coots, Common Moorhens, and Purple Gallinules:

Wisconsin Zone:

Season Dates: Begin 15 days prior to opening of regular State duck season. End with closure of State duck season.

Daily Bag and Possession Limits: 15 daily, singly or in aggregate. Possession limit 30.

Michigan Zone:

Season Dates: Same dates permitted Michigan under final Federal frameworks.

Daily Bag and Possession Limits: 15 daily, singly or in aggregate. Possession limit 30.

Michigan and Wisconsin Zones: Sora and Virginia Rails. Season Dates: September 15 through November 19.

Daily Bag and Possession Limits: 25 daily, singly or in aggregate. Possession limit 25.

Common Snipe.

Season Dates: September 15 through November 19.

Daily Bag and Possession Limits: 8 daily. Possession limit 16.

Woodcock.

Season Dates: September 15 through November 19.

Daily Bag and Possession Limits: 5 daily. Possession limit 10. D. General Conditions

(1) Tribal members will comply with all basic Federal migratory Bird hunting regulations, 50 CFR Part 20, and shooting hour regulations, 50 CFR Part 20, Subpart K.

(2) Nontoxic shot will be required for all off-reservation waterfowl hunting by

tribal members.

(3) Wisconsin Zone. Tribal members will comply with sec. NR 10.09(1)(a) (2) and (3), Wis. Adm. Code (shotshells), sec. NR 10.12(1)(c), Wis. Adm. Code (shooting from structures), sec. NR 10.12(1)(g), Wis. Adm. Code (decoys), and sec. 29.27, Wis. Stats. (duck blinds).

(4) Wisconsin and Michigan Zones. Tribal members will comply with State regulations providing for closed and restricted waterfowl hunting areas.

(5) Possession limits are applicable only to transportation and do not include birds which are cleaned, dressed, and at a member's primary residence. For purposes of enforcing bag and possession limits, all migratory birds in the possession or custody of tribal hunters on ceded lands will be considered to have been taken on those lands unless tagged by a tribal or State conservation warden as taken onreservation. In Wisconsin, such tagging shall comply with sec. NR 19.12, Wis. Adm. Code. All migratory birds which fall on reservation lands will not count as part of any off-reservation bag or possession limit.

7. Shoshone-Bannock Tribes, Fort Hall Indian Reservation, Fort Hall, Idaho

The tribes on this reservation in southeastern Idaho have developed a major waterfowl hunting program for nontribal members. Although most of the reservation is Indian land, some land within its boundaries is owned by non-Indians and provides waterfowl hunting. The State claims authority to establish hunting regulations for non-Indians on these lands, whereas the tribes claim jurisdiction over hunting on all lands within the boundaries of the reservation. The question of jurisdiction became an issue last year when it

became necessary for the Service to reduce the length of the duck season, and the tribes opposed the split season established by the State. However, following consultation with the Service, the State concurred with the tribes, and a continuous duck season was established throughout the reservation in the 1985–86 hunting season.

On May 19, 1986, Service representatives from the Portland. Oregon, Regional Office met with tribal and State officials for the purpose of reaching general agreement on waterfowl hunting regulations for the 1986-87 hunting season. However, an agreement has not yet been reached that is acceptable to the Shoshone-Bannock Tribes, the State, and the Service. The Service intends to continue these consultations. Pending concurrence, the Service proposes to establish final waterfowl hunting regulations similar to those established last year on the reservation and to publish them in an August 1986, Federal Register.

Public Comment Invited

Based on the results of recently completed migratory game bird studies, and having due consideration for any data or views submitted by interested parties, this proposed rulemaking may result in the adoption of special hunting seasons for migratory game birds beginning as early as September 1, 1986, on certain Federal Indian reservations, Indian Territory, and ceded lands. Taking into account both reserved hunting rights and the degree to which tribes have recognized full management authority, the regulations for tribal or for both tribal and nontribal members may differ from those established by States in which the reservations, Indian Territory, and ceded lands are located. The regulations will specify open seasons, shooting hours, and bag and possession limits for rails, gallinules (including moorhen), woodcock, snipe, band-tailed pigeons, mourning doves, white-winged doves, ducks, and geese.

The Director intends that finally adopted rules be as responsive as possible to all concerned interests. Therefore, he desires to obtain the comments and suggestions on these proposals from the public, other concerned governmental agencies, tribal and other Indian organizations, and private interests, and he will take into consideration the comments received. Such comments, and any additional information received, may lead the Director to adopt final regulations differing from these proposals.

Special circumstances in the establishment of these regulations limit the amount of time that the Service can allow for public comments. Two considerations compress the time in which this rulemaking process must operate: The need, on the one hand, for tribes and the Service to establish final regulations before September 1, 1986. and on the other hand, the unavailability before late July of specific reliable data on this year's status of waterfowl. Therefore, the Service believes that to allow a comment period past August 14, 1986 is contrary to the public interest.

Comment Procedure

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may participate by submitting written comments to the Director, (FWS MBMO), U.S. Fish and Wildlife Service, Department of the Interior, Room 536, Matomic Building, Washington, DC 20240. Comments received will be available for public inspection during normal business hours at the Service's Office in Room 536 in the Matomic Building, 1717 H Street, NW., Washington, DC 20240. All relevant comments on the proposals received no later than August 14, 1986 will be considered

NEPA Consideration

The "Final Environmental Statement for the Issuance of annual Regulations Permitting the Sport Hunting of Migratory Birds (FES-75-74)" was filed with the Council on Environmental Quality on June 6, 1975, and notice of availability was published in the Federal Register on June 13, 1975 (40 FR 25241). In addition, an August 1985, environmental assessment entitled "Guidelines for Migratory Bird Hunting Regulations on Federal Indian Reservations and Ceded Lands" is available from the Service.

Nontoxic Shot Regulations

On January 6, 1986 (at 51 FR 409), the Service proposed nontoxic shot zones for the 1986–87 waterfowl hunting season. This proposed rule was sent to all affected tribes and to Indian organizations for comment. A preliminary final rule on the 1986–87 nontoxic shot zones was appended to the "Final Supplemental Environmental Impact Statement (FES 86–16) on the Use of Lead Shot for Hunting Migratory Birds in the United States," that was published in July 1986. The final rule on nontoxic shot zones for the 1986–87 hunting season will be published in the Federal Register in mid-August, following completion of the Record of Decision on the supplement.

Endangered Species Act Consideration

Section 7 of the Endangered Species
Act provides that, "The Secretary shall
review other programs administered by
him and utilize such programs in
furtherance of the purposes of this Act"
[and] "by taking such action necessary
to insure that any action authorized,
funded or carried out . . . which is
determined to be critical."
Consequently, the Service has initiated
section 7 consultation under the
Endangered Species Act for the
proposed hunting seasons on Federal
Indian Reservations, Indian Territory,
and ceded lands.

Regulatory Flexibility Act and Executive Order 12291

In the Federal Register dated March 21, 1986, (51 FR 9860), the Service reported measures it had undertaken to comply with requirements of the Regulatory Flexibility Act and the Executive Order. These included preparing a Determination of Effects and an updated Final Regulatory Impact Analysis, and publication of a summary of the latter. These regulations have been determined to be major under Executive Order 12291 and they have a significant economic impact on substantial numbers of small entities under the Regulatory Flexibility Act. This determination is detailed in the aforementioned documents which are available upon request from the Office of Migratory Bird Management, U.S. Fish and Wildlife Service, Room 536, Matomic Building, Washington, DC 20240. As noted in the March 21, 1986. Federal Register the Service plans to issue its Memorandum of Law for migratory hunting regulations at the same time the first of the annual hunting rules is completed. This rule does not contain any information collection requiring approval by OMB under 44 U.S.C 3504.

Authorship

The primary author of this proposed rulemaking is Fant W. Martin, Office of

Migratory Bird Management, working under the direction of Rollin D. Sparrowe, Chief.

List of Subjects in 50 CFR Part 20

Hunting, Wildlife, Exports, Imports, Transportation.

The rules that eventually will be promulgated for the 1986–87 hunting season are authorized under the Migratory Bird Treaty Act of July 3, 1918 (40 Stat. 755; 16 U.S.C. 703 et. seq.), as amended.

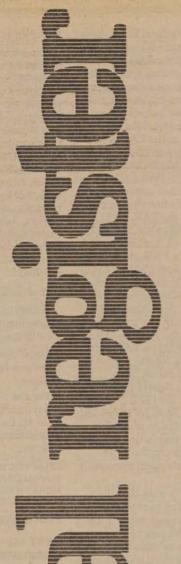
Dated: July 24, 1986.

Susan Recce,

Deputy Assistant Secretary for Fish and
Wildlife and Parks.

[FR Doc. 86–17046 Filed 7–29–86; 8:45 am]

BILLING CODE 4310-55-M



Wednesday July 30, 1986

Part VII

Office of Personnel Management

48 CFR Ch. 16

Federal Employees Health Benefits Acquisition Regulation; Proposed Rule

OFFICE OF PERSONNEL MANAGEMENT

48 CFR Ch. 16

Federal Employees Health Benefits Acquisition Regulation

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: This regulation describes the method by which the U.S. Office of Personnel Management (OPM) implements and supplements the Federal Acquisition Regulation (FAR) for the Federal Employees Health Benefits (FEHB) Program. OPM is proposing this regulation to identify basic and significant acquisition policies unique to the FEHB Program. The regulation would be referred to as the Federal Employees Health Benefits Acquisition Regulation (FEHBAR).

DATE: Comments must be received on or before September 15, 1986.

ADDRESS: Written comments may be sent to Reginald M. Jones, Assistant Director for Retirement and Insurance Policy, Retirement and Insurance Group, Office of Personnel Management, P.O. Box 57, Washington, DC 20044, or delivered to Room 4351, 1900 E Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mary Ann Mercer, (202) 632-0003.

SUPPLEMENTARY INFORMATION: On October 20, 1981, OPM published a final rule in the Federal Register [46 FR 51566-51582] to provide direction and uniformity in the agency's procurement of health benefits plans and to enable the health benefits carriers and other interested parties to understand the application of the Federal Procurement Regulations (41 CFR Chapter 1) to the FEHBP. Subsequently, the FAR System was established for the codification and publication of uniform policies and procedures for acquisition by all executive agencies. The FAR system consists of those government-wide acquisition regulations in 48 CFR Chapter 1 and agency acquisition regulations in subsequent chapters issued by individual agencies. OPM is now proposing the FEHBAR, established as Chapter 16 within Title 48 of the Code of Federal Regulations, to describe the method by which it will implement and supplement the FAR for the specific purpose of acquiring and administering contracts with health insurance carriers in the FEHBP.

The fundamental principle underlying the FEHBAR is that the FAR is applicable *in general* to contracts

negotiated under the Federal Employees Health Benefits Program although specific application of the FAR necessarily differs from its application to other procurement contracts because of the distinctive nature of the service procured, i.e., health care coverage. Indeed, it is well understood that a number of provisions of the FAR would be impossible to apply literally in a practical manner to a health benefits contract. In accord with FAR Subpart 1.3, the FEHBAR does not unnecessarily repeat, paraphrase, or otherwise restate material contained in the FAR. Therefore, the FEHBAR is not, by itself, a complete document as it must be used in conjunction with the FAR. Where the FAR has no practical applicability to the FEHBP and attempts to apply a given provision would be counterproductive and inconsistent with the intent of the FAR, specific notation is provided along with the authority for the determination of nonapplicability. Where a FAR Part or Subpart is adequate for use without further OPM implementation or supplementation, or is clearly irrelevant, no mention is cited in the FEHBP. Thus, the order of use is (1) FAR; (2) FEHBAR. The FEHBAR is intended to identify basic and significant acquisition policies unique to the FEHBAR. (In the main, these policies were published previously as 41 CFR Chapter 16.)

It is also important to note that the FEHBAR is not intended to replace, incorporate, or supplement regulations found at 5 CFR Part 890 and 5 CFR Part 891 which provide the substantive policy guidance for administration of the health benefits programs under 5 U.S.C. Chapter 89 and Pub. L. 86–724, 74 Stat. 849.

Reduction of Comment Period for Proposed Rulemaking

OPM has determined that the comment period will be 45 days because of the desire to have the regulations in place as early as possible for the calendar year 1986 FEHB Program.

E.O. 12291, Federal Regulation

OPM has determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation implements and supplements the Federal Acquisition Regulation (FAR), which has already been established for entities contracting with the Federal Government.

Paperwork Reduction Act

The recordkeeping and reporting requirements contained in this proposal (1604.705 and 1615.6) have been submitted to OMB for review under section 3504(h) of the Paperwork Reduction Act of 1980. Comments on the requirements should be submitted to the Office of Information and Regulatory Affairs (OMB), New Executive Office Building, Room 3001, Washington, DC 20503; Attention: Desk Officer for the Office of Personnel Management. A copy should be submitted to Jean M. Barber, Assistant Director for Pay and Benefits Policy, Compensation Group, Office of Personnel Management, 1900 E. Street, NW., Room 4351, Washington, DC 20415.

List of Subjects in 48 CFR Chapter 16

Administrative practice and procedure, Government contracts, Health insurance.

Office of Personnel Management, Constance Horner,

Director

For the reasons set out in the preamble, OPM is proposing to amend Title 48, Code of Federal Regulations, by establishing Chapter 16 to read as follows:

CHAPTER 16—OFFICE OF PERSONNEL MANAGEMENT, FEDERAL EMPLOYEES HEALTH BENEFITS ACQUISITION REGULATION

SUBCHAPTER A-GENERAL

PART 1601—FEDERAL ACQUISITION REGULATIONS SYSTEM

Subpart 1601.1—Purpose, Authority, Issuance

Sec

1601.101 Purpose. 1601.102 Authority

1601.103 Applicability.

1601.104 Issuance.

1601.104-1 Publication and code arrangement.

1601.104–2 Arrangement of regulations. 1601.105 OMB approval under the Paperwork Reduction Act.

Subpart 1601.3—Agency Acquisition Regulation (FEHBAR)

1601.301 Policy.

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

Subpart 1601.1—Purpose, Authority, Issuance

1601.101 Purpose.

(a) This subpart establishes Chapter 16, Office of Personnel Management Federal Employees Health Benefits Acquisition Regulation, within Title 48, the Federal Acquisition Regulation System, of the Code of Federal Regulations. The short title of this regulation shall be FEHBAR.

(b) The purpose of the FEHBAR is to implement and supplement the Federal Acquisition Regulation (FAR) specifically for acquiring and administering contracts with health insurance carriers in the Federal Employees Health Benefits Program (FEHBP).

1601.102 Authority.

The FEHBAR is issued by the Director of the Office of Personnel Management in accordance with the authority of 5 U.S.C. Chapter 89 and other applicable law and regulation.

1601.103 Applicability.

The FAR is generally applicable to contracts negotiated in the FEHBP pursuant to 5 U.S.C. Chapter 89. The FEHBAR implements and supplements the FAR where necessary to identify basic and significant acquisition policies unique to the FEHBP.

1601.104 Issuance.

1601.104-1 Publication and code arrangement.

- (a) The FEHBAR and its subsequent changes are published in—
- (1) Daily issues of the Federal Register and
- (2) Cumulative form of the Code of Federal Regulations.
- (b) The FEHBAR is issued as Chapter 16 of Title 48 of the Code of Federal Regulations.

1601.104-2 Arrangement of regulations.

- (a) General. The FEHBAR conforms with the arrangement and numbering system prescribed by FAR 1.104. However, when a FAR part or subpart is adequate for use without further OPM implementation or supplementation, there will be no corresponding FEHBAR part, subpart, etc. The FEHBAR is to be used in conjunction with the FAR and the order for use is:
 - (1) FAR; (2) FEHBAR.
- (b) Citation. (1) In formal documents, such as legal briefs, citation of Chapter 16 material that has been published in the Federal Register will be to Title 48 of the Code of Federal Regulations.
- (2) In informal documents, any section of Chapter 16 may be identified as "FEHBAR" followed by the section number.

1601.105 OMB approval under the Paperwork Reduction Act.

The Paperwork Reduction Act of 1980 (Pub. L. 96-511) requires Federal agencies to obtain approval from the

Office of Management and Budget (OMB) before collecting information from ten or more members of the public. The information collection and recordkeeping requirements contained in this regulation have been approved by the OMB. The following OMB control numbers apply.

Provision	Control No.
FEHBAR 1604.705	
FAR 9.1	

Subpart 1601.3—Agency Acquisition Regulation (FEHBAR)

1601.301 Policy.

- (a) Procedures, contract clauses, and other aspects of the acquisition process for contracts in the FEHBP shall be consistent with the principles of the FAR. Changes to the FAR that are otherwise authorized by statute or applicable regulation, dictated by the practical realities associated with the unique nature of health care procurements, or necessary to satisfy specific needs of the Office of Personnel Management shall be implemented as amendments to the FEHBAR and published in the Federal Register, or as deviations to the FAR in accordance with FAR Subpart 1.4.
- (b) Internal procedures, instructions, and guides which are necessary to clarify or implement the FEHBAR within OPM may be issued by agency officials specifically designated by the Director, OPM. Normally, such designations will be specified in the OPM Administrative Manual which is routinely available to agency employees and will be made available to interested outside parties upon request. Clarifying or implementing procedures, instructions, and guides issued pursuant to this section of the FEHBAR must:
- (1) Be consistent with the policies and procedures contained in this regulation as implemented and supplemented from time to time; and
- (2) Follow the format, arrangement, and numbering system of this regulation to the extent practicable.

PART 1603—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

Subpart 1603.70—Misleading, Deceptive, or Unfair Advertising

1603.701 Policy.

1603.702 Additional guidelines. 1603.703 Contract clause.

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

Subpart 1603.70—Misleading, Deceptive, or Unfair Advertising

1603.701 Policy.

- (a) OPM prepares and distributes to Federal employees and annuitants a comparison booklet which presents objective factual information about benefits, limitations, and premium rates for all participating plans. For this reason, OPM does not encourage, support, or reimburse participating carriers for the costs of advertisements. However, while OPM believes that advertising is unnecessary, it recognizes that the decision to use advertising rests with each carrier.
- (b) Advertising which is misleading or deceptive is damaging to Federal employees and annuitants because it can encourage them to enroll in health plans which are unsuited to their needs. Unfair advertising is that which is directed at other plans participating in the Program through the use of incomplete or inappropriate comparisons or disparaging or minimizing techniques. Such unfair practices are prejudicial to the interests of the vast majority of carriers whose advertising is fair and accurate.
- (c) A carrier shall advertise its health plan only in a manner which is consistent with the most recent publication of the "Rules Governing Advertisements of Accident and Sickness Insurance with Interpretive Guidelines" published by the Model Regulation Service, National Association of Insurance Commissioners, and this subpart.
- (d) Failure to conform to the requirements of this subpart shall be a material breach of the contract and may result in withdrawal of approval to continue participation in the FEHB Program.

1603.702 Additional guidelines.

- (a) Advertisements shall discuss the merits of the carrier's plan and shall be limited to factual statements of the benefits and rates offered by that plan. Advertisements shall not—
- (1) Compare a plan's benefits and rates with those of any other plan. (The comparison chart issued by OPM is the official document for comparisons.)
- (2) Include statements or comments which express support or criticism of any Governmental policy, or person or political cause.
- (b) The FEHBP logo shall not be used on any advertising material.
- (c) The officially approved plan brochure is the sole contractual statement of benefits, limitations and exclusions. All advertisements which in

any way discuss plan benefits shall contain the following statement:

This is a summary (or brief description) of the features of the (plan's name). Before making a final decision, please read the plan's officially approved brochure, (brochure number). All benefits are subject to the definitions, limitations, and exclusions set forth in the official brochure.

- (d) All advertisements which discuss benefits shall set forth the rates for the plan.
- (e) Advertisements shall not give instructions on enrollment. Statements on enrollment procedures, requirements, or eligibility shall be limited to those such as "see your employing office for open season enrollment information."

1603.703 Contract clause.

The clause at 1652.203-70 shall be inserted in all FEHBP contracts.

PART 1604—ADMINISTRATIVE MATTERS

Subpart 1604.7—Contractor Records Retention

1604.703 Policy. 1604.705 Specific retention periods.

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

Subpart 1604.7—Contractor Records Retention

1604.703 Policy.

In view of the unique payment schedules of FEHBP contracts and the compelling need for records retention periods sufficient to protect the Government's interest, contractors shall be required to maintain records for periods determined in accordance with the provisions of FAR 4.703(b)(1).

1604.705 Specific retention periods.

Unless the contracting officer determines that there exists a compelling reason to include only the contract clause specified by FAR 52.215–2, all FEHBP contracts will have the following statement added to the clause specified by FAR 52.215–2:

Notwithstanding the provisions of paragraph (d) above, carriers will retain and make available all records applicable to a contract year which support the annual statement of operations for that year until either an audit is made and a final audit report is issued, or the contracting officer and the carrier agree upon the amount of contract charges and reflect this agreement by mutually relieving each party and the FEHBP contract from further liabilities or claims for the applicable period.

PART 1605—PUBLICIZING CONTRACT ACTIONS

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

1605.000 Applicability.

FAR Part 5 has no practical application to the FEHBP because OPM does not issue solicitations. Eligible contractors (i.e., qualified health benefits carriers) are identified in accordance with 5 U.S.C. 8903. Offerors voluntarily come forth in accordance with procedures provided in 5 CFR Part 890.

PART 1606—COMPETITION REQUIREMENTS

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

1606.001 Applicability.

FAR Part 6 has no practical application to FEHBP contracts in view of the statutory exception provided by 5 U.S.C. 8902.

Subchapter C—Contracting Methods and Contract Types

PART 1614—SEALED BIDDING

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

1614.000 Applicability.

FAR Part 14 has no practical application to FEHBP contracts in view of the statutory exemption provided by 5 U.S.C. 8902.

PART 1615—CONTRACTING BY NEGOTIATION

Subpart 1615.1—General Requirements for Negotiation

1615.170 Negotiation authority.

Subpart 1615.4—Solicitations and Receipt of Proposals and Quotations

1615.401 Applicability.

Subpart 1615.6-Source Selection

1615.602 Applicability.

Subpart 1615.8—Price Negotiation

1615.802 Policy.

1615.804-70 Certificate of community rating. 1615.805-70 Carrier investment of FEHB funds.

1615.805-71 Investment income clause.

Subpart 1615.9-Profit

1615.902 Policy.

1615.905 Profit analysis factors.

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

Subpart 1615.1—General Requirements for Negotiation

1615.170 Negotiation authority.

The authority to negotiate FEHBP contracts is conferred by 5 U.S.C. 8902.

Subpart 1615.4—Solicitations and Receipt of Proposals and Quotations

1615.401 Applicability.

FAR Subpart 15.4 has no practical application to the FEHBP because OPM does not issue solicitations. Eligible contractors (i.e., qualified health benefits carriers) are identified in accordance with 5 U.S.C. 8903. Offerors voluntarily come forth in accordance with procedures provided in 5 CFR Part 890.

Subpart 1615.6-Source Selection

1615.602 Applicability.

FAR Subpart 15.6 has no practical application to the FEHBP because prospective contractors (carriers) are considered for inclusion in the FEHBP in accordance with criteria provided in 5 U.S.C. Chapter 89 and 5 CFR Part 890 rather than on the basis of competition between prospective carriers.

Subpart 1615.8—Price Negotiation

1615.802 Policy.

Pricing of FEHB contracts is governed by 5 U.S.C. 8902(i), 5 U.S.C. 8906, and other applicable law. FAR Subpart 15.8 shall be implemented by applying the policies and procedures—to the extent practicable—as follows:

- (a) Cost analysis for contracts where premiums and subscription income are determined on the basis of experience rating; and
- (b) Price analysis for contracts where premiums and subscription income are determined on the basis of community rating.
- (c) The application of FAR 15.802(b)(2) should not be construed to prohibit the consideration of preceding year surpluses or deficits in carrier-held reserves in the rate adjustments for subsequent year renewals of contracts based on cost analysis.

1615.804-70 Certificate of community rating.

As soon as possible after completing negotiations, each carrier proposing a community rate shall submit the following certification signed by an official authorized to execute the contract:

Certificate of Community Rating (Apr 1985)

(a) This is to certify that the proposed subscription rate(s), subject to adjustments recognized by OPM, is a community rate(s).

(b) If it is determined that the subscription rate, subject to the allowable adjustments, is not a community rate, the Government shall be entitled to an adjustment of the price in accordance with the clause at FEHBAR 1652.215–70. Price reduction for Defective Certificate of Community Rating.

0.00000.	
Organization: -	
Certifying official:	
Title:	
Date: —	
(End of certificate)	

1615.805-70 Carrier Investment of FEHB funds.

(a) The carrier is required to invest and reinvest all funds on hand, including any in the special reserve or any attributable to the reserve for incurred but unpaid claims, exceeding the funds needed to discharge promptly the obligations incurred under the contract.

(b) Investment income. Investment income is the net amount earned by the carrier after deducting investment expenses.

1615.805-71 Investment income clause.

The clause set forth in 1632.215-71 shall be inserted in all contracts based on cost analysis.

Subpart 1615.9-Profit

1615.902 Policy.

(a) OPM will determine the profit or fee prenegotiation objective (service charge) portion of FEHBP contracts by use of a weighted guidelines structured approach when the pricing of such contracts is determined by cost analysis. The service charge so determined will be the total service charge that may be negotiated for the contract and will encompass any service charge (whether entitled service charge, profit, fee, contribution to reserves or surpluses, or any other title) that may have been negotiated by the prime contractor with any subcontractor or underwriter.

(b) OPM will not guarantee a minimum service charge.

1615.905 Profit Analysis Factors.

(a) OPM contracting officers will apply a weighted guidelines method in developing the service charge prenegotiation objective for FEHBP contracts. The following factors as defined in FAR 15.905–1 will be applied

to projected incurred claims and allowable administrative expenses:

(1) Contractor performance—OPM will consider such elements as the accurate and timely processing of benefit claims and the volume and validity of disputed claims as measures of economical and efficient contract performance. This factor will be judged apart from the contractor's basic responsibility for contract performance and will be a measure of the extent and nature of the contractor's contribution to the FEHBP through the application of managerial expertise and effort. Minimal contract performance will receive a zero weight; evidence of effective performance a plus weight; and poor performance or failure to comply with contract terms and conditions a negative weight.

(2) Contract cost risk-OPM will consider such underwriting elements as the availability of margins, group size, enrollment demographics and fluctuation, and the probability of conversion and adverse selection, in assessing the degree of cost responsibility and associated risk assumed by the contractor as a factor in negotiating profit. It should be noted that the "loss carry forward basis" of experience rated group insurance practices limits this factor in an overall determination of profit. This factor is intended to provide profit opportunities commensurate with the contractor's share of cost risks, only, taking into account such elements as the adequacy and reliability of data for estimating costs, etc., offset by the "loss carry forward basis" of experience rating.

(3) Federal socioeconomic programs-OPM will consider documented evidence of successful, contractor-initiated efforts to support such Federal socioeconomic programs as drug and substance abuse deterrents, and other concerns of the type enumerated in FAR 15.905-1(c) as a factor in negotiating profit. This factor will be related to the quality of the contractor's policies and procedures and the extent of unusual effort or achievement demonstrated. Participation that is merely satisfactory or required by statute or contract clause shall be assigned a weight of zero, generally; evidence of effective support a plus weight; and poor support a negative weight.

(4) Capital investments—This factor is generally not applicable to FEHBP contracts since facilities capital cost of money may be an allowable administrative expense. Generally, this factor shall be given a weight of zero. However, special purpose facilities or investments costs of direct benefit to the

FEHBP that are not recoverable as allowable or allocable administrative expenses may be taken into account in assigning a plus weight.

(5) Cost control—OPM will consider contractor-initiated efforts such as coordination of benefits, improved benefit design, cost-sharing features, and innovative peer review or other professional cost containment efforts as a factor in negotiating profit. This factor shall be used to reward contractors with additional profit opportunities for selfiniated efforts to control contract costs. Merely performing tasks required and implementing features directed by OPM shall receive a zero weight; innovations of benefit to the FEHBP generally a plus weight; documented inattention or indifference to cost control a negative

(6) Independent development—OPM will consider any profit opportunities that may be directly related to relevant independent efforts such as the development of a unique and enhanced customer support system that is of demonstrated value to the FEHBP and for which developmental costs have not been recovered directly or indirectly through allowable administrative expenses. This factor will be used to provide additional opportunities based upon an assessment of the contractor's investment and risk in developing techniques, methods, practices, etc., having viability to the program at large. Improvements and innovations recognized and rewarded under any of the other profit factors can not be considered.

(b) The weight ranges for each factor to be used in the weighted guidelines approach are set forth below:

Profit factor	Weight ranges (in percent)
Contractor performance	1 to +.4
2. Contract cost risk 1	+.02 to +.2
3. Federal socioeconomic programs	05 to +.05
4. Capital investments	0 to +.02
5. Cost control	1 to +.3
6. Independent development	0 to +.03

¹ The contract cost risk factor is subdivided into two parts: group size (.02 to .10) and other risk elements (0 to .10), with respect to the group size element, subweights should be assigned as follows:

Enrollment	Weight (in percent)
10,000 or less	.06 to .10
10,001-50,000	.05 to .09
50,001-200,000	
200,001-500,000	
500,001 and over	.02 to .04

PART 1616—TYPES OF CONTRACTS

Subpart 1616.1—Selecting Contract Types

1616.102 Policies.

1616.105 Solicitation provision.

Subpart 1616.2—Fixed-Price Contracts

1616.270 Clause—contracts based on established catalog or market price. 1616.271 Clause—contracts based on cost analysis.

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1,301.

Subpart 1616.1—Selecting Contract Types

1616.102 Policies.

(a) FEHBP contracts in which benefits provided and subscription income are based on community rating shall be negotiated fixed price contracts with economic price adjustments.

(b) FEHBP contracts in which benefits provided and subscription income are based on experience rating shall be a combination of negotiated fixed price contracts with provisions for a form of retroactive price redetermination.

1616.105 Solicitation provision.

FAR 16.105 has no practical application since the statutory provisions of 5 U.S.C. Chapter 89 obviate the issuance of solicitations.

Subpart 1616.2—Fixed-Price Contracts

1616.270 Clause—contracts based on established catalog or market price.

The clause at 1652.216-70 shall be inserted in all FEHBP contracts based on established catalog or market price.

1616.271 Clause—contracts based on cost analysis.

The clause at 1652.216-71 shall be inserted in all FEHBP contracts based on cost analysis.

Subchapter D—Socioeconomic Programs

PART 1622—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

Subpart 1622.1—Basic Labor Policies

1622.103-70 Contract clause.

The clause at 1652.222-70 shall be inserted in all FEHBP contracts with Comprehensive Medical Plans.

PART 1624—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

Authority: U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

Subpart 1624.1—Protection of Individual Privacy

1624.104 Contract clauses.

Records retained by FEHBP carriers on Federal subscribers and members of their families serve the carriers' own commercial function of paying health benefits claims and are not maintained to accomplish an agency function of OPM. Consequently, the records to not fall within the provisions of the Privacy Act. Nevertheless, OPM recognizes the need for carriers to keep certain records confidential. The clause at 1652.224–70 shall be inserted in all FEHBP contracts.

Subchapter E—General Contracting requirements

PART 1631—CONTRACT COST PRINCIPLES AND PROCEDURES

Subpart 1631.2—Contracts With Commercial Organizations

1631.201-70 FEHBP credits. 1631.203-70 FEHBP General and

Administrative (G&A) expenses. 1631.205 Selected costs.

1631.205-70 FEHBP advertising costs. 1631.205-71 FEHBP bad debts.

1631.205–71 FEHBP bad debts. 1631.205–72 FEHBP compensation for

personal services. 1631.205–73 FEHBP interest expense.

1631.205-74 FEHBP losses on other contracts. 1631.205-75 FEHBP professional and

consultant service costs.

1631.205–76 Selling costs.
1631.205–77 Trade, business, technical and professional activity costs.

1631.205-78 FEHBP start-up and other nonrecurring costs.

1631.205-79 FEHBP printed material costs. 1631.205-80 Reinsurance premiums and stop loss insurance.

1631.205-81 Mandatory statutory reserves. 1631.205-82 Major subcontractor service charges.

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

Subpart 1631.2—Contracts With Commercial Organizations

1631.201-70 FEHBP credits.

The provisions of FAR 31.201-5 shall apply to income, rebates, allowances, and other credits resulting from benefit payments that include, but are not limited to:

- (a) Coordination of benefit refunds:
- (b) Hospital year-end settlements;
- (c) Uncashed and returned checks;
- (d) Utilization review refunds;
- (e) Refunds attributable to litigation with subscribers or providers of health services; and
- (f) Erroneous benefit payment, overpayment, and duplicate payment recoveries.

1631.203-70 FEHBP General and Administrative (G&A) expenses.

The provisions of FAR 31.203 apply to the allocation of G&A type costs by means of a "dividend or retention formula."

1631.205 Selected costs.

1631.205-70 FEHBP advertising costs.

- (a) The cost of media messages which are directed at advising current FEHBP subscribers on how to obtain benefits shall be an allowable expense within the meaning of FAR 31.205–1 since this service is directly related to performance of the FEHBP contract. If there is any question about the allowability of such a cost, the carrier may request advance approval regarding the content and cost of the message.
- (b) Costs of media messages not provided for in paragraph (a) of this section are allowable if the content is specifically approved by the contracting officer and all of the following criteria are met:
- (1) The primary effect of the message is to disseminate information on health care cost containment or preventive health care;
- (2) The costs of the carrier's messages are allocated to all underwritten and non-underwritten lines of business; and
- (3) The contracting officer approves the total dollar amount of the carrier's messages in advance of the contract year.

Costs of messages which are intended to, or which have the primary effect of, calling favorable attention to the carrier (or subcontractor) for the purpose of enhancing its overall image or selling its health plan are not allowable.

1631.205-71 FEHBP bad debts.

Erroneous benefit payments are not automatically disallowed by FAR 31.205-3.

1631.205-72 FEHBP compensation for personal services.

Overtime on an FEHBP contract would normally meet the condition specified in FAR 22.103. Premiums for overtime, extra-pay shifts, and multishifts meeting the specified conditions shall be allowed without prior approval.

1631.205-73 FEHBP interest expense.

(a) Interest charges incurred in the administration of FEHBP contracts are not allowable in accordance with FAR 31.205–20. However, interest charges which are associated with the carrier's investment of FEHBP account funds are not considered administrative costs and may be allowable under very limited

circumstances if all of the following criteria are met:

- (1) Borrowing is limited to the positive balance of the carrier's FEHBP Special Reserve:
- (2) FEHBP funds are tied up in long term securities;
- (3) Liquidation of long-term securities would cost more than the cost of the interest:
- (4) The interest rates charged are at or below current market rates; and
- (5) Advance written approval of the contracting officer is obtained before such costs are incurred.
- (b) The carrier must demonstrate on a case-by-case basis that borrowing rather than cashing in long-term investments shall actually result in cost savings to the FEHB Program.

 Satisfactory demonstration of cost savings is a prerequisite to contracting officer approval of the interest cost as a charge to the contract.
- (c) If the interest charge is allowed, the risk factor in the service charge will be adjusted downward so that the carrier does not recover interest costs through both the service charge and an allowance under this paragraph.

1631.205-74 FEHBP losses on other contracts.

FAR Subpart 31.205–23 shall not be construed to prohibit the application of the normal "loss carry forward" principle which is fundamental to continuing insurance contracts that are based on experience rating.

1631.205-75 FEHBP professional and consultant service costs.

FAR 31.205–33(d) makes unallowable the costs of prosecution of claims against the Government. The costs associated with appealing a final decision of the contracting officer to the Board of Contract Appeals or the U.S. Claims Court shall not be allowable charges to the contract.

1631.205-76 Selling costs.

(a) FAR 31.205-38 is modified to eliminate from allowable costs those costs related to sales promotion and the payment of sales commissions and fees to employees or outside commercial or selling agencies for enrolling Federal subscribers in a particular FEHBP plan.

(b) Selling costs are allowable costs to FEHBP contacts to the extent that they are necessary for conducting annual contract negotiations with the Government and for liaison activities necessary for ongoing contract administration. Personnel and related travel costs are allowable for attendance at open season health fairs and other similar activities sponsored

by Government agencies (but see FAR 31.205-1 "Advertising costs", and Federal Personnel Manual Supplement 890-1, Subchapter S2-3(f) "Controlling contracts between employees and carriers.")

1631.205-77 Trade, business, technical and professional activity costs.

- (a) FEHBP participating plans, carriers, and underwriters shall seek the advance written approval of the contracting officer for allowability of costs associated with trade, business, technical and professional activities (FAR 31.205-43) where the allocable costs of such participation to the FEHBP will exceed \$1,000 annually.
- (b) Where approval of costs for membership in an organization whose membership is comprised primarily of carriers and/or underwriters participating in the FEHB Program is requested, the carrier or underwriter must demonstrate conclusively that membership in such an organization and participation in its activities are a benefit to the FEHB Program and FEHB enrollees.

1631.205-78 FEHBP start-up and other nonrecurring costs.

Precontract costs (FAR 31.205–31) shall be allowed only to the extent provided for by advance agreement in accordance with FAR 31.109.

1631.205-79 FEHBP printed material costs.

Unless OPM determines that it is in the best interest of the FEHBP to do otherwise, if a carrier orders printed material that is available from the Government Printing Office (GPO) under the "rider system" from another source, the allowable contract charges shall be the lesser of the amount actually paid or the cost that would have been incurred had the carrier ridden OPM's GPO order.

1631.205-80 Reinsurance premiums and stop loss insurance.

Charges for acquiring reinsurance or stop loss protection are not allowed without the contracting officer's written approval.

1631.205-81 Mandatory statutory reserves.

Charges for mandatory statutory reserves are not allowed unless provided for in the contract.

1631.205-82 Major subcontractor service charges.

In a subcontract for enrollment and eligibility determinations, administration of claims and payment of benefits or provision of actual health services, and/or assumption of insurance risk or underwriting, any amount that exceeds the allowable cost of the subcontract (whether entitled service charge, profit, fee, contribution to reserve, surplus, or any other title) is not allowable under the contract.

PART 1632—CONTRACT FINANCING

Subpart 1632.1-General

1632.111 Contract clause.1632.170 Coordination of benefits clause.

Subpart 1632.6-Contract Debts

1632.607 Tax credit.

1632.617 Contract clause.

Subpart 1632.7—Contract Funding

1632.770 Contingency reserve payments. 1632.771 Non co-mingling of FEHBP funds.

1632.772 Contract clause.

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

Subpart 1632.1—General

1632.111 Contract clause.

The funding provisions of 5 U.S.C. 8909 obviate the need for carriers to submit invoices or vouchers.
Consequently, the clause at FAR 52.232-1 shall be modified in all FEHBP contracts to delete the phrase "upon the submission of proper invoices or vouchers" and insert "within thirty days after receipt of premiums by the Federal Employees Health Benefits Fund."

1632.170 Coordination of benefits clause.

The clause at 1652.232-70 shall be included in all FEHBP contracts.

Subpart 1632.6-Contract Debts

1632.607 Tax credit.

FAR 32.607 has no practical application to FEHBP contracts. The statutory provisions at 5 U.S.C. 8906 (c) and (d) authorize joint enrollee and Government contributions to the FEHB Fund. Because the Fund is comprised of contributions by enrollees as well as the Government, carriers may not offset debts to the Fund by a tax credit which is solely a Government obligation.

1632.617 Contract clause.

The clause at FAR 52.232–17 will be modified in FEHBP contracts based on established catalog or market price to exclude the words "net of any applicable tax credit under the Internal Revenue Code (26 U.S.C. 1481)."

Subpart 1632.7—Contract Funding

1632.770 Contingency reserve payments.

(a) Payments from the contingency reserve shall be made in accordance with 5 CFR 890.503. (b) A carrier for an FEHB plan may apply to OPM at any time for a payment from the contingency reserve which is in addition to those amounts, if any, paid under 5 CFR 890.503(c)(1) through (c)(4), if the carrier can show good cause, such as, unexpected adverse claims experience. A determination to allow the payment in whole or in part shall be at the sole discretion of OPM. However, OPM shall not unreasonably withhold approval for amounts requested which exceed the plan's preferred minimum halance.

1632.771 Non co-mingling of FEHBP funds.

- (a) Carrier or underwriter co-mingling of FEHBP funds with those from other sources results in the inability to precisely determine FEHBP cash balances at any given time or to precisely determine investment income attributable to FEHBP invested assets.
- (b) FEHBP funds shall be maintained separately from other cash and investments of the carrier or underwriter. Cash balances reported on FEHBP Annual Accounting Statements must be reconcilable to the carrier's books and records. The reconciliation schedule shall be included as a supporting schedule to the Annual Accounting Statement.
- (c) This requirement may be waived by the contracting officer in accordance with the clause at 1652.232-71.

1632.772 Contract clause.

The clause at 1652.232-71 shall be included in all contracts which are based on cost analysis.

PART 1633—PROTESTS, DISPUTES, AND APPEALS

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

1633.070 Designation of the Board of Contract Appeals.

The Armed Services Board of Contract Appeals (ASBCA) serves as the Board of Contract Appeals for the FEHBP. The rules of procedure followed in a dispute shall be those prescribed by the ASBCA.

PART 1644—SUBCONTRACTING POLICIES AND PROCEDURES

Subpart 1644.1-General

1644.170 Policy for FEHBP subcontracting consent.

Subpart 1644.2—Consent to Subcontracts

1644.270 FEHBP contract clause.

Authority: 5 U.S.C. 8913; 40 U.S.C. 488(c); 48 CFR 1.301.

Subpart 1644.1—General

1644.170 Policy for FEHBP subcontracting consent.

For FEHBP contracts based on cost analysis, advance approval shall be required on all subcontracts or modifications to subcontracts which meet the criteria specified in both paragraphs (a) and (b) of this section:

- (a) The amount charged the FEHBP contract exceeds \$100,000; and
- (b) The purpose of the subcontract is to provide for the administration of the carrier's FEHBP plan. Administration is defined as any one or more of the following functions:
- Subscriber enrollment and eligibility determination;
- (2) Adjudication and payment of benefits; and/or
 - (3) Underwriting.

Subpart 1644.2—Consent To Subcontracts

1644.270 FEHBP contract clause.

The clause set forth at 1652.244-70 shall be inserted in all FEHBP contracts based on cost analysis.

PART 1646—QUALITY ASSURANCE

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

Subpart 1646.3—Contract Clauses

1646.301 Contractor inspection requirements.

The clause set forth at 1652.246-70 shall be inserted in all FEHBP contracts.

PART 1649—TERMINATION OF CONTRACTS

1649.000-70 Applicability of the FAR to FEHB acquisitions.

Subpart 1649.1—General Principles

1649.101-70 FEHB renewal and withdrawal of approval clause.

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

1649.000-70 Applicability of the FAR to FEHB acquisitions.

Termination of FEHBP contracts is controlled by 5 U.S.C. 8902(e) and 5 CFR 890.205. The procedures for settlement of contracts after they are terminated shall be those contained in FAR Part 49.

Subpart 1649.1—General Principles

1649.101-70 FEHB renewal and withdrawal of approval clause.

The clause in 1652.249–70 shall be inserted in all FEHB contracts.

Subchapter H-Clauses and Forms

PART 1652—CONTRACT CLAUSES

1652.000-70 Applicable clauses.

Subpart 1652.2—Texts of FEHBP Clauses

1652.203-70 Misleading, deceptive or unfair advertising.

1652.215-70 Price reduction for defective certificate of community rating.

1652.215-71 Investment income. 1652.216-70 Accounting and price adjustment.

1652.216-71 Accounting and allowable cost.

1652.222-71 Notice of significant events. 1652.224-70 Confidentiality of records.

1652.232-70 Coordination of benefits. 1652.232-71 Non co-mingling of FEHBP funds.

1652.244-70 Subcontracts.

1652.246-70 FEHB inspection.

1652.249–70 Renewal and withdrawal of approval.

Subpart 1652.3—FEHBP Clause Matrix

1652.370 Use of the matrix.

Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

1652.000-70 Applicable clauses.

The clauses of Subpart 52.2 specified below shall be applicable to FEHB acquisitions.

Section	Clause Title
52:202-1	Definitions (APR 1985).
52.203-1	
52.203-3	
52.203-5	Covenant Against Contingent Fees (APR 1985).
52.215-1	
	Comptroller General (APR 1985).
52.215-2 1604.705	Audit—Negotiation (APR 1985).
52.215-22	Price Reduction for Defective
	Cost of Pricing Data (APR 1985).
52.215-23	Price Reduction for Defective
	Cost or Pricing Data Modifi- cations (APR 1985).
52.215-24	Subcontractor Cost or Pricing Data (APR 1985).
52.215-25	Subcontractor Cost or Pricing
	Data—Modifications (APR 1985).
52.215-30	Facilities Capital Cost of Money (APR 1985).
52.215-31	Waiver of Facilities Capital
52.219-8	Cost of Money (APR 1985).
52.219-0	Utilization of Small Business Concerns and Small Disad-
	vantaged Business Con-
	cerns (APR 1985).
52.219-13	Utilization of Women-Owned
	Small Businesses (APR 1985).
52.220-3	Utilization of Labor Surplus Area Concerns (APR 1985).
52.222-1	
	Labor Disputes (APR 1985).
52.222-2	Payment for Overtime Premi- ums (APR 1985).
52.222-3	Convict Labor (APR 1985).
52.222-4	Contract Work Hours and
	Safety Standards Act—Over-
	time Compensation—Gener- al (APR 1985).
52.222-26	Equal Opportunity (APR 1985).
52.222-28	Equal Opportunity Preaward
	Clearance of Subcontracts (APR 1985).
52 222-29	Notification of Visa Denial

Section	Clause Title
52 222-35	Affirmative Action for Special
DE EEE-OO	Disabled and Vietnam Era
52.222-36	Veterans (APR 1985).
52.222-30	Affirmative Action for Handi- capped Workers (APR
	1985).
52.223-2	Clean Air and Water (APR
	1985).
52.229-3	Federal, State, and Local Taxes (APR 1985).
52.229-4	Federal State, and Local
	Taxes (Noncompetitive Con-
1000	tract) (APR 1985).
52.229-5	Taxes—Contracts Performed
	in U.S. Possessions or Puerto Rico (APR 1985).
52 229-6	Taxes—Foreign Fixed-Price
	Contracts (APR 1985).
52.230-3	Cost Accounting Standards
CO 000 4	(APR 1985). Administration of Cost Ac-
52.230-4	Administration of Cost Ac- counting Standards (APR
	1985).
52.230-5	Disclosure and Consistency of
	Cost Accounting Practices
	(APR 1985).
52.230-8	Ing Practices (APR 1985).
52.232-1 1632.111	Payments (APR 1985).
52.232-8	
	(APR 1985).
52.232-11	
52.232-17 1632.617 52.232-23	
52.232-23	1985).
52.232-24	Prohibition of Assignment of
	Claims (APR 1985).
52.233-1	Disputes (APR 1985).
52.242-1	
52.243-1	Costs (APR 1985). Changes—Fixed Price—Atter-
	nate I (APR 1985).
52.244-1	Subcontracts Under Fixed-
	Price Contracts (APR 1985).
52.244-5	Competition in Subcontracting (APR 1985).
52.245-2	Government Property (Fixed-
	Price Contracts) (APR 1985).
52.246-25	Limitation of Liability-Services
	(APR 1985).
52.247-63	Preference for U.SFlag Air
52.251-1	Carriers (APR 1985). Government Supply Sources
Vacable 1 minimum mini	(APR 1985).
52.252-2	Clauses Incorporated by Ref-
State of	erence (APR 1985).
52.252-4	Alterations in Contract (APR
52.252-6	1985). Authorized Deviations in
SC-132 S (00000000000000000000000000000000000	Clauses (APR 1985).

Subpart 1652.2—Texts of FEHBP Clauses

1652.203-70 Misleading, deceptive, or unfair advertising.

As prescribed in 1603.703, the following clause shall be inserted in all FEHBP contracts:

Misleading, Deceptive or Unfair Advertising (APR 1984)

(a) The Carrier agrees that any advertising material, including that labeled promotional material, marketing material, or supplemental literature, shall adhere to the most recent publication of the "Rules Governing Advertisements of Accident and Sickness Insurance with Interpretive Guidelines" published by the Model Regulation Service, National Association of Insurance Commissioners, and the additional guidelines set forth in 1603.702.

(b) This clause shall be included in all subcontracts which exceed \$25,000.

(End of Clause)

1652.215-70 Price reduction for defective certificate of community rating.

As prescribed in 1615.804-70, the following clause shall be inserted in contracts based on established catalog or market price:

Price Reduction For Defective Certificate of Community Rating (APR 1985)

(a) If it is determined that the subscription rate(s), subject to the adjustments recognized by OPM is not a community rate, the Government shall be entitled to an adjustment of the price so that it is a true community rate. If the Carrier cannot determine a true community rate, OPM shall require the Carrier to charge a rate for that contract period that does not exceed the lowest rate charged by the Carrier to another group or groups with similar benefits for similar contract periods.

(b) If the price of the adjusted community rate, or the lowest rate charged to another group, is less than the original subscription price, the price of this contract shall be reduced accordingly. At the discretion of the Contracting Officer, refunds due the Government shall be returned to the Government for deposit in the FEHB Fund, used to reduce future FEHBP subscription charges of the Carrier, or used to offset Contingency Reserve payments to the Carrier.

(c) When the Contracting Office determines that the Carrier submitted a defective community rate and the Government is entitled to a refund under paragraph 1652.215-70(b), the refund shall bear interest from the date the overcharge was paid by the Government to the Carrier until the date the overcharge is liquidated as provided in 1652.215-70(b). In calculating the amount of interest due, the semiannual rate determinations by the Secretary of the Treasury under the authority of the Renegotiation Act of 1951 (50 U.S.C., para. 1211, et. seq.) applicable to the periods the overcharge was retained by the Carrier shall be used.

(End of Clause)

1652.215-71 Investment income.

As prescribed in 1615.805–71, the following clause shall be inserted in all FEHBP contracts based on cost analysis:

Investment Income (APR 1985)

(a) The Carrier shall invest and reinvest all FEHBP funds on hand which are in excess of the funds needed to promptly discharge the obligations incurred under this contract. The Carrier shall seek to maximize investment income with due consideration to the safety and liquidity of investments.

(b) All investment income earned on FEHBP funds shall be credited to the Special Reserve on behalf of the FEHBP.

(c) When the Contracting Officer concludes that the Carrier has failed to comply with paragraphs (a) or (b) of this clause, the Contracting Officer may direct the Carrier to credit the Special Reserve with investment income that would have been earned at the

rate(s) specified in paragraph (e) had it not been for the Carrier's noncompliance. "Failed to comply with paragraphs (a) or (b)" means failure to place excess funds, including refunds, credits, payments, deposits, investment income earned, or other amounts owed the Special Reserve, in income producing investments and accounts. Interest income shall be due for the period from the date the Carrier failed to invest the funds until the date the Carrier invests such funds.

(d) On charges for benefits, administrative expenses, and other items, made by the Carrier which are subsequently determined to be unallowable, interest shall be charged from the date of the Contracting Officer's notification of disallowance of the cost to the date the funds are deposited in the Special Reserve.

(e) If directed, the Carrier shall credit the Special Reserve for income due in accordance with this clause. In calculating the amount of the interest credit due the FEHBP, the semiannual rate determinations by the Secretary of the Treasury under authority of the Renegotiation Act of 1951 (50 U.S.C. App., para. 1211, et. seq.) applicable to the period of noncompliance shall be used. (End of Clause)

1652.216-70 Accounting and price adjustment.

As prescribed in 1616.270, the following clause shall be inserted in all FEHBP contracts based on established catalog or market price:

Accounting and Price Adjustment (APR 1985)

(a) Annual Accounting Statement. The Carrier not later than 90 days after the end of each contract period, shall furnish to OPM for that contract period an accounting of its operations under the contract. The accounting shall be in the form prescribed by OPM.

(b) Adjustment. (1) This contract is community rated. The amounts agreed upon by OPM and the Carrier represent a rate equivalent to that charged to the total community rated membership of the Carrier during the period of this contract for the same level of health benefits plus or minus those amounts mutually agreed upon by OPM and the Carrier for those factors, benefits, or requirements of OPM that are not a component in determining the Carrier's community rate.

(2) If during the contract period the Carrier establishes a community rate higher than the rate established for the contract period and the rate increase is made effective on the same calendar date in all other group health benefits contracts held by the Carrier, OPM agrees to pay the Carrier an amount equal to the product of—

(i) The increase in the rates that has been produced by the community rate increase, multiplied by

(ii) The number of subscribers determined by OPM, multiplied by

(iii) The number of months between the effective date of the increase and the end of the contract period during which the rates apply

(3) Amounts payable under this subsection may, at the discretion of the Contracting Officer, be paid to the Carrier by-

(i) Paying all or part of the amount from funds available in the Contingency Reserve (or as funds become available in later contract periods); or

(ii) Accepting an additional loading to the rates for the earliest possible contract period following the community rate increase; or

(iii) Establishing a reimbursement schedule combining elements of both (i) and (ii) of this

subparagraph.

(4) If during the contract period the Carrier establishes a community rate that is lower than the rate agreed upon for the contract benefit period or if the agreed upon rate is based on an anticipated community rate increase which exceeds the actual community rate increase established for the contract period, the Carrier agrees to accept an adjustment to the agreed upon rate that is calculated to recover the amount of the excess charged under this contract as a result of the lower community rate. At the discretion of the Contracting Officer, refunds due the Government shall be (i) returned to the Government for deposit in the FEHB Fund; (ii) used to reduce future FEHBP subscription charges of the Carrier; or (iii) used to offset Contingency Reserve payments to the Carrier.

(End of Clause)

1652.216-71 Accounting and allowable cost.

As prescribed in 1616.271, the following clause shall be inserted in all FEHBP contracts based on cost analysis:

Accounting and Allowable Cost (APR 1985)

(a) Annual Accounting Statement. (1) The Carrier, not later than 90 days after the end of each contract period, shall furnish to OPM for that contract period an accounting of its operations under the contract. The accounting shall be in the form prescribed by OPM and shall include, among other things, the following items for each option provided by the contract:

(i) Subscription charges received and accrued (including those received from the

Contingency Reserve): (ii) Health benefits charges;

(iii) Expenses and other charges;

(iv) Income on Investments;

(v) Sum of items (i) minus (ii) minus (iii)

plus (iv). (2) Based on the results of audit, the Carriers' annual accounting statements may

be (i) reduced by amounts found not to constitute allowable costs; or (ii) adjusted for prior overpayments or underpayments.

(b) Allowable cost. The allowable costs chargeable to the contract for a contract period shall be the actual, necessary amounts incurred in the administration of this contract, with proper justification and accounting support, determined in accordance with Subpart 31.2 of the Federal Acquisition Regulation (FAR) and Subpart 1631.2 of the Federal Employee Health Benefits Acquisition Regulation (FEHBAR) applicable on the first day of the contract

(End of Clause)

1652.222-70 Notice of significant events.

As prescribed in 1622,103-70, the following clause shall be inserted in all FEHBP contracts with Comprehensive Medical Plans:

Notice of Significant Events (APR 1985)

(a) The Carrier agrees to notify the OPM of any Significant Event within ten (10) working days after the Carrier becomes aware of it. As used in this Section, a Significant Event is any occurrence of anticipated occurrence which might reasonably be expected to have a material effect upon the Carrier's ability to meet its obligations under this contract, including, but not limited to, any of the following:

(1) Disposal of major assets:

(2) Loss of 15% or more of the Carrier's

overall membership;

(3) Termination or modification of any contract or subcontract if such termination or modification will have a material effect on the Carrier's obligations under this contract;

(4) The imposition of, or notice of the intent to impose, a receivership, conservatorship or

special regulatory monitoring;

(5) The withdrawal of, or notice of intent to withdraw, State licensing, HHS qualification, or any other status under Federal or State law:

(6) Default on a loan or other financial obligation;

(7) Strikes, slowdowns or the substantial impairment of the Carrier's facilities or of other facilities used by the Carrier in the performance of this contract.

(b) Upon learning of a Significant Event, the OPM may institute action as it deems necessary to protect the interest of subscribers, including, but not limited to:

(1) Suspending new enrollments under this contract:

(2) Advising subscribers of the Significant Event and providing them an opportunity to transfer to another Carrier;

(3) Terminating the enrollment of those subscribers who, in the judgment of OPM, would be adversely affected by the Significant Event; or

(4) Terminating this contract pursuant to Article V.

(End of Clause)

1652.224-70 Confidentiality of records.

As prescribed in 1624.104, the following clause shall be inserted in all FEHBP contracts:

Confidentiality of Records (APR 1985)

(a) The Carrier shall use the personal data on employees and annuitants that is provided by agencies and OPM, including social security numbers, for only those routine uses stipulated for the data and published annually in the Federal Register as a part of OPM's notice of systems of records.

(b) The Carrier shall also hold all medical records, and information relating thereto, of Federal subscribers and family members

confidential except as follows:

(1) As may be reasonably necessary for the administration of this contract;

(2) As authorized by the patient or his or her guardian;

(3) As disclosure is necessary to permit Government officials having authority to investigate and prosecute alleged criminal actions;

(4) As necessary to audit the contract;

(5) As necessary to carry out the coordination of benefits provisions of this contract; and

(6) For bona fide medical research or educational purposes. Release of information for medical research or educational purposes shall be limited to aggregated information of a statistical nature that does not identify any individual by name, social security number, or any other identifier unique to an individual.

(c) If the carrier uses medical records for the administration of the contract, or for bona fide medical research or educational purposes, it shall so state in the plan's brochure.

(End of Clause)

1652.232-70 Coordination of benefits.

As prescribed in 1632.170, the following clause shall be inserted in all FEHBP contracts:

Coordination of benefits (April 1985)

(a) Primary-Secondary status. Where applicable, the Carrier agrees to coordinate, on a primary-secondary basis, the payment of benefits under this contract with the payment of benefits under other group health benefits coverages and the payment of medical and hospital costs under no-fault automobile

(b) As used in this Section, the term "group health benefits coverage" includes all forms of group coverage under which payment is made for hospital, medical, or other health services and supplies; the term "no-fault automobile insurance" includes automobile insurance under which benefits are payable by the insurer for the expenses of hospital and medical care of injuries resulting from an automobile accident without regard to whether the insured's negligence contributed to the accident, and the term "Health Benefits Coverage" shall refer to group health benefits coverage and no-fault automobile insurance. The term "Primary Carrier" for purposes of this Section means the Carrier unless one or more other organizations are determined to be a Primary Carrier under any of the following rules, in which case the Carrier shall not be the Primary Carrier:

(1) Governmental programs:

(i) Medicare. In the event benefits are payable to the subscriber under Title XVIII of the Social Security Act ("Medicare"), Medicare shall be regarded as a Primary Carrier except as provided hereafter. Medicare shall not be regarded as the Primary Carrier of benefits in those cases in which Medicare is made secondary by 42 CFR 405.327 (end stage renal disease), or by 42 CFR 405.341 (working aged).

(ii) CHAMPUS and Medicaid. In the event benefits are payable to the subscriber under the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), CHAMPUS shall not be regarded as the

Primary Carrier, and in the event benefits are payable to the subscriber under Title XIX of the Social Security Act ("Medicaid"). Medicaid shall not be regarded as the

Primary Carrier.

(2) In the event benefits are payable to the subscriber under no-fault automobile insurance, the no-fault automobile insurer shall be the Primary Carrier if it is obligated to pay benefits for health care without regard to other Health Benefits Coverages which the subscriber may have.

(3) In the event benefits are payable to the subscriber under any Health Benefits Coverage other than this contract, the Primary Carrier shall be the organization which is the only one which satisfies the first one of the following tests (in the order set forth) by providing Health Benefits Coverage to the subscriber:

(i) As an active employee, a member of an

organization, or a student.

(ii) As a retired employee or a survivor annuitant, except that if the other Health Benefits Coverage does not coordinate benefits similarly for retired employees, the Primary Carrier shall be determined under subparagraph (b)(3)(vii) of this section.

(iii) As a child of a male active employee, or member of an organization, or student, unless the male parent is separated or divorced. In that case, the Primary Carrier shall be the organization which is the only one which satisfies the first one of the three following tests (in the order set forth) by providing Health Benefits Coverage to the subscriber:

(A) As child of the parent with custody; (B) As child of the stepparent, in the event

the parent with custody has remarried; (C) As child of the parent without custody; Notwithstanding the above, if there is a court decree which would otherwise establish financial responsibility for the medical, dental, or other health care expenses with respect to the child, the Primary Carrier shall be the organization which provides Health Benefits Coverage to the subscriber as a dependent of the person with such financial

responsibility.

(iv) As a child of a male retired employee or of a male survivor annuitant, unless the male parent is divorced or separated. In that case, the Primary Carrier shall be determined under the provisions of subparagraph (b)(3)(iii) of this section. If the other Health Benefits Coverage does not similarly provide for children of retired employees, the Primary Carrier shall be determined under subparagraph (b)(3)(vii) of this section.

(v) As dependent (other than a child) of an

active employee.

(vi) As dependent (other than a child) of a retired employee or of a survivor annuitant, except that if the other Health Benefits Coverage does not coordinate benefits similarly for retired employees, the Primary Carrier shall be determined under subparagraph (b)(3)(vii) of this section.

(vii) Under which the subscriber has been continuously covered longer than by any

other such coverage.

(4) Whenever the benefits payable to the subscriber under any other Health Benefits Coverage are payable without regard to the benefits payable under this contract, the Carrier shall not be the Primary Carrier.

(c) The Carrier shall make a reasonable effort to determine the extent of duplicate coverage for each subscriber. Where the Carrier has evidence of other Health Benefits Coverage, the Carrier shall make a diligent effort to determine the amount of benefits

(d) In no event shall the subscriber receive under this contract and all other Health Benefits Coverage more than the total reasonable actual expense or cost of the benefits and services covered by this contract. If the Carrier makes payment to a subscriber or heir(s) under this contract in excess of the amount required by this provision, the Carrier shall make a reasonable effort to obtain a refund of the excess from the subscriber or heir(s). (End of Clause)

1652.232-71 Non co-mingling of FEHBP funds.

As prescribed in 1632,772, the following clause shall be inserted in all contracts based on cost analysis.

Non Co-Mingling of Funds (April 1985)

(a) The Carrier shall keep all FEHBP funds (cash and investments) physically separate from funds obtained from other sources. Accounting for such FEHBP funds shall not be based on allocations or other sharing mechanisms and shall be reconcilable to the Carrier's accounting records. Cash balances and investment income reported to OPM on the Annual Accounting Statements must be supported by reconciliation schedules which clearly define differences between cash and investment balances reported and amounts recorded on a Carrier's accounting records.

(b) In certain instances the physical separation of FEHBP funds may not be practical or desirable. In such cases, the Carrier may request a waiver from this requirement from the Contracting Officer. The waiver shall be requested in advance and the Carrier shall demonstrate that accounting techniques have been established which will clearly measure FEHBP cash and investment income (i.e., subsidiary ledgers). Reconciliations between amounts reported and actual amounts shown in accounting records shall be provided as supporting schedules to the Annual Accounting Statements.

(c) This clause shall be included in all subcontracts which exceed \$25,000. (End of clause)

1652.244-70 Subcontracts.

As prescribed by 1644,270, the following clause shall be inserted in all FEHBP contracts based on cost analysis:

Subcontracts (April 1985)

(a) The Carrier shall notify the Contracting Officer reasonably in advance of entering into any subcontract or subcontract modification, or as otherwise specified by this contract, if the amount of the subcontract or modification charged to the FEHB Program exceeds \$100,000 and provides for the administration of the Carrier's FEHB plan. Administration is defined as (1) subscriber enrollment and eligibility determinations, (2)

adjudication and payment of benefits and claims, and/or (3) underwriting.

(b) The advance notification required by paragraph (a) of this clause shall include the information specified below:

(1) A description of the supplies or services to be subcontracted:

(2) Identification of the type of subcontract

(3) Identification of the proposed subcontract and an explanation of why and how the proposed subcontractor was selected, including the competition obtained;

(4) The proposed subcontract price and the

Carrier's cost or price analysis;

(5) The subcontractor's current, complete, and accurate cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions;

(6) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract;

(7) A negotiation memorandum reflecting-

(i) The principal elements of the subcontract price negotiations;

(ii) The most significant consideration controlling establishment of initial or revised

(iii) The reason cost or pricing data were or

were not required;

(iv) The extent, if any, to which the Carrier did not rely on the subcontractor's cost or pricing data in determining the price objective and in negotiating the final price;

(v) The extent to which it was recognized in the negotiation that the subcontractor's cost or pricing data were not accurate, complete, or current; the action taken by the Carrier and the subcontractor; and the effect of any such defective data on the total price negotiated;

(vi) The reasons for any significant difference between the Carrier's price objective and the price negotiated; and

(vii) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(c) The Carrier shall obtain the Contracting Officer's written consent before placing any subcontract for which advance notification is required under paragraph (a) of this clause. However, the Contracting Office may ratify in writing any such subcontract. Ratification shall constitute the consent of the Contracting Officer.

(d) The Contracting Officer may waive the requirement for advance notification and consent required by paragraphs (a). (b) and (c) of this clause where the Carrier and subcontractor submit an application or renewal as a contractor team arrangement as defined in FAR Subpart 9.6 and:

(1) The Contracting Officer evaluated the arrangement during negotiation of the contract or contract renewal; and

(2) The subcontractor's price and/or costs were included in the plan's rates which were reviewed and approved by the Contracting

Officer during negotiation of the contract or contract renewal.

(e) Unless the consent or approval specifically provides otherwise, consent by the Contracting Officer to any subcontract shall not constitute a determination (1) of the acceptability of any subcontract terms or conditions; (2) of the allowability of any cost under this contract; or (3) to relieve the Carrier of any responsibility for performing this contract.

(f) No subcontract placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis. Any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.903(d).

(g) The Carrier shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Carrier by any subcontractor or vendor that, in the opinion of the Carrier, may result in litigation related in any way to this contract with respect to which the Carrier may be entitled to reimbursement from the Government. (End of Clause)

1652.246-70 FEHB Inspection.

As prescribed in 1646.301, the following clause shall be inserted in all FEHBP contracts:

FEHB Inspection (April 1985)

The Government has the right to inspect and evaluate the work performed or being performed under the contract, and the premises where the work is being performed, at all reasonable times and in a manner that will not unduly delay the work. If the Government performs inspection or evaluation on the premises of the Carrier or a subcontractor, the Carrier shall furnish and require the subcontractor to furnish all reasonable facilities and assistance for the safe and convenient performance of these duties.

(End of Clause)

1652.249-70 Renewal and withdrawal of approval.

As prescribed in 1649.101-70, the following clause shall be inserted in all FEHBP contracts:

Renewal and Withdrawal of Approval (April, 1985)

(a) The contract renews automatically for a term of one (1) year each January first, unless written notice of non-renewal is given either by OPM or the Carrier not less than 60 Calendar days before the renewal date, or unless modified by mutual agreement.

(b) This contract also may be terminated at other times by order of OPM pursuant to 5 U.S.C. 8902(e). Pending termination, OPM may take action as it deems necessary to protect the interests of enrollees, including but not limited to:

(1) Suspending new enrollments under the contract:

(2) Advising enrollees of the asserted deficiencies; and

(3) Providing enrollees an opportunity to transfer to another plan.

(c) OPM may, after proper notice, terminate the contract at the end of the contract term if it finds that the Carrier did not have at least 300 subscribers enrolled in its plan at any time during the two preceeding contract periods.

(End of Clause)

Subpart 1652.3—FEHBP Clause Matrix

1652,370 Use of the matrix.

(a) The martrix in this section lists the FAR and FEHBAR clauses to be used with contracts based on cost analysis and contracts based on established catalog or market price. Carriers shall submit initial applications and requests for renewals on the basis that the new contract or contract renewal will include the clauses indicated.

(b) Certain contract clauses are mandatory for FEHBP contracts. Other clauses are to be used only when made applicable by pertinent sections of the FAR or FEHBAR. An "M" in the "Use Status column indicates that the clause is mandatory. An "A" indicates that the clause is to be used only when the applicable conditions are met.

(c) Clauses are incorporated in the contract either in full text or by reference. If the full text is to be used, the matrix indicates a "T". If the clause is incorporated by reference, the matrix indicates an "R".

FEHBP CLAUSE MATRIX

Clause No. Text reference		Use status	Use with contracts based on		
	Title		Cost analysis	Established catalog or market price	
AR 52.202-1	FAR 2.2	Definitions	M	R	R
AR 52.203-1	FAR 3.102-2	Officials Not to Benefit	M	R	R
AR 52.203-3	FAR 3.202	Gratuities	M	B	R
AR 52.203-5	FAR 3.404(c)	Covenant Against Contingent Fees	M	B	R
652.203-70	1603,703	Misleading, Deceptive or Unfair Advertising	100	B	R
AR 52.215-1	FAR 15.106-1(b)	Examination of Records by Comptroller General		B	12.40
AR 52.215-2		Audit—Negotiation		T	R
	(Modification: 1604.705).	CHOIL TO GUARANT	M	Bea sel	
AR 52.215-22	FAR 15.804-8(a)	Price Reduction for Defective Cost or Pricing Data	M	R	1 C 3 D 1 3 B
AR 52.215-23	FAR 15.804-8(b)	Price Reduction for Defective Cost or Pricing Data—Modifications	N.		R
AR 52.215-24	FAR 15.804-8(c)	Subcontractor Cost or Pricing Data.		R	
AR 52.215-25	FAR 15.804-8(d)	Subcontractor Cost or Pricing Data—Modifications	100	10	R
AR 52.215-30	FAR 15.904	Facilities Capital Cost of Money	24	R	10
AR 52.215-31	FAR 15.904	Waiver of Facilities Capital Cost of Money	A	R	
652.215-70		Price Reduction for Defective Certificate of Community Rating		H	-
652.215-71	1615.805-71	Investment income		D.	R
652.216-70		Accounting and Price Adjustment.		B	1200
652.216-71	1616.271	Accounting and Allowable Cost	M	-	R
AR 52.219-8		Utilization of Small Business Concerns and Small Disadvantaged Business Concerns		R	OLD THE REAL PROPERTY.
AR 52.219-13	FAR 19.902	Utilization of Women-Owned Small Businesses	M	R	R
AR 52.220-3		Utilization of Labor Surplus Area Concerns	M	R	B
AR 52.222-1		Notice to the Government of Labor Disputes	M	R	R
AR 52.222-2	FAR 22.103-5(b)	Power to the Government of Capor Disputes	A.1	R	
AR 52.222-3	FAR 22.202	Payment for Overtime Premiums	M	R	and the
AR 52 222-4		Convict Labor	M	R	R
AR 52.222-26	FAR 22.810(e)	Contract Work Hours and Safety Standards Act—Overtime Compensation—General	M	R	R
AR 52.222-28	FAR 22.810(g)	Equal Opportunity	M	R	A
AR 52.222-29	FAR 22.810(h)		M	R	R
AR 52.222-35	FAR 22.1308(a)	Notification of Visa Denial	A	R	R
AR 52.222-36			M	R	R
652.222-70			M	R	R
AR 52.223-2	1622.103-70	Notice of Significant Events	A =	R	R
652.224-70	FAR 23.105(b)		M	R	R
	1624.104	Confidentiality of Records	M	R	R
AR 52.229-3	FAR 29.401-3	Federal, State and Local Taxes	M	Maria Colombia	R
AR 52.229-4		Federal, State and Local Taxes (Noncompetitive Contract)	M	R	The second second
AR 52.229-5		Taxes—Contracts Performed in U.S. Possessions or Puerto Dico	A CONTRACTOR OF THE CONTRACTOR	R	R
AH 52.229-6	I FAH 29.402-1(a)	Taxes—Foreign Fixed Price Contracts	A	B	B

FEHBP CLAUSE MATRIX—Continued

Land State of the land of the			100000	Use with cont	racts based or
Clause No. Text reference	Title	Use status	Cost analysis	Established catalog or market price	
R 52.230-3	FAR 30.303-2(a)(1)	Cost Accounting Standards	A	R	R
R 52.230-4	FAR 30.303-2(b)(1)	Administration of Cost Accounting Standards	A	0	R
R 52.230-5	FAR 30.303-2(c)(1)	Disclosure and Consistency of Cost Accounting Practices	A	B	R
R 52.230-6		Consistency in Cost Accounting Practices	1	R	H
	FAR 32.111(a)(1)	Payments	2	0	4
	(Modification: 1632.111).		M		1
R 52.232-8	FAR 32.111(c)(1)	Discounts for Prompt Payment	М	R	R
R 52.232-11	FAR 32.111(d)(2)	Extras	M	B	B
R 52.232-17	FAR 32.617(a)	Interest	W.	-	n T
The same of the sa	(Modification: 1632.617).		(M)	TO SECOND	
R 52.232-23	FAR 32.806-(a)(1)	Assignment of Claims	M	R	R
R 52.232-24	FAR 32.806(b)	Prohibition of Assignment of Claims	A	R	R
52.232-70	1632.170	Coordination of Benefits	M	n	R
	1632.772	Non Co-mingling of FEHBP Funds.	M	0	H
R 1652.233-1	FAR 33.014	Disputes	NA.	B	R
R 52.242-1	FAR 42.802	Notice of Intent to Disallow Costs	44	R	H
	FAR 43.205(a)(1)	Changes—Fixed-Price—Alternate I	M	8	-
	FAR 44.204(a)(1)(i)	Subcontracts Under Fixed-Price Contracts	M	15	R
	1644.270	Subcontracts	N.	R	B
	FAR 44.204(e)	Competition in Subcontracting	M	120	-
	FAR 45.106(b)(1)	Government Property (Fixed Price Contracts)	M	R	A
R 52.246-25	FAR 46.805(a)	Limitation of Liability Services	M	R	R
	1646.301	FEHB Inspection	M	H	
	FAR 47.405	Preference for U.SFlag Air Carriers	M	H	R
52 249-70	1649.101-70	Renewal and Withdrawal of approval	M	R	B
		Government Supply Sources	M	R	R
		Clauses incorporated by Reference	0	R	
			M	1	T
			M		1

Applies to Employee Organization and Government-wide Plans.
Applies to all Comprehensive Medical Plans.

PART 1653-FORMS

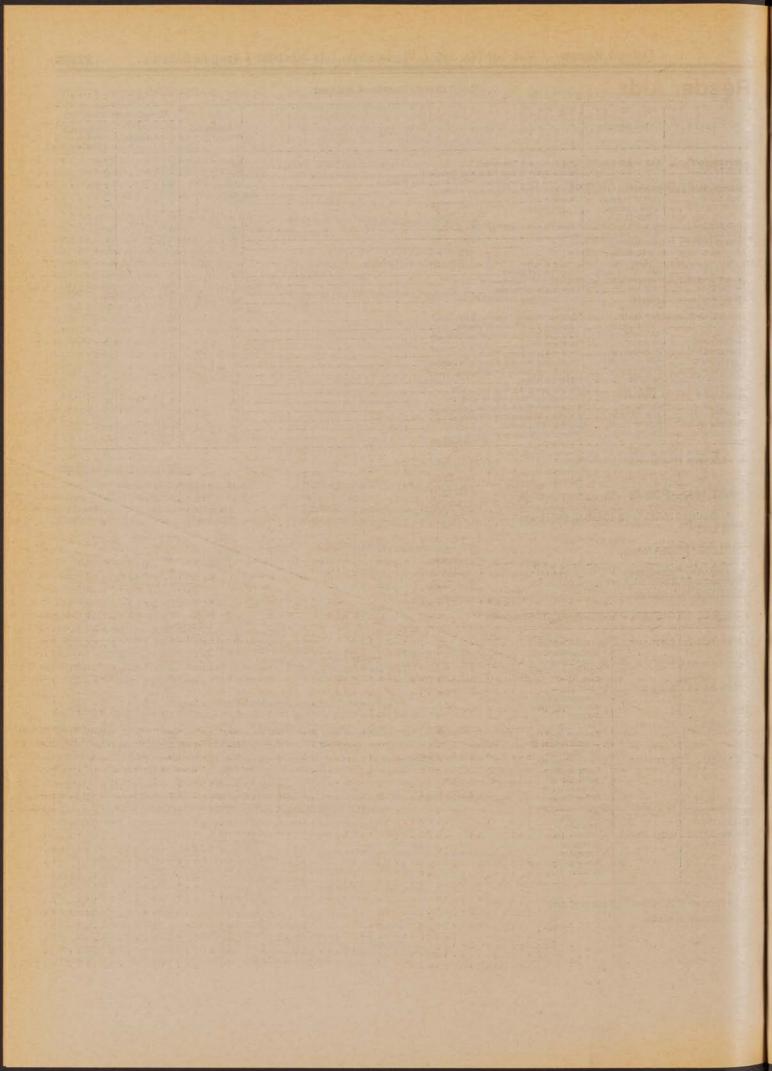
Authority: 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

1653.000 FEHBP forms.

The following forms specified in FAR Subparts 53.2 and 53.3 are applicable to FEHBP acquisitions:

Part 53.2	Part 53.3	Form title
53.201-1	53.301-1402	SF 1402—Certificate of Appointment.
53.203	53.301-119	
53.204-2(a)		Individual Contract Action Report (over \$10,000).
53.204–2(b)	12 12 13	Summary of Contract Actions of \$10,000 or less.
	. 53.301-1412	SF 1412—Claim for Exemption from Submission of Certified Cost or Pricing Data.
53.229	53.301-1094	SF 1094—U.S. Tax Exemption Certificate.
53.229	. 53.301-1094A	SF 1094A—Tax Exemption Certificates Accountability Record.

[FR Doc. 86-17002 Filed 7-29-86; 8:45 am] BILLING CODE 6325-01-M



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